

EPA Reg. Jacket 2724-481 vol 1

Figure 1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Gary Sandberg
Wellmark International
1501 E. Woodfield Road, Suite 200 W
Schaumburg, IL 60173

SEP 22 2005

Dear Mr. Sandberg:

Subject: Amendment: Change source of manufacturing
Tau-Fluvalinate Technical
EPA Registration Number 2724-481
Your submission dated April 15, 2005

Dear Mr. Sandberg:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable. All the product chemistry data submitted corresponding to 830 Series Subgroup A and Subgroup B are acceptable. The Confidential Statement of Formula dated March 7, 2005 is acceptable. Please note that this acceptance is conditional and subject to the Agency's final determination regarding the toxicological significance of the new impurities identified for material produced at the new manufacturing site. The Agency notes that you have provided justifications and arguments to demonstrate that these new impurities are not of toxicological significance. The revised labeling showing the increase in the declared percentage of active ingredient is acceptable and a stamped copy is enclosed for your records.

Sincerely,

George LaRocca.
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Manufacturing process information may be entitled to confidential treatment

TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Tau-fluvalinate (CAS #102851-06-9)

93.7%

Deleted: 87.2

OTHER INGREDIENTS:

6.3%

Deleted: 12.8

TOTAL 100.0%

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA

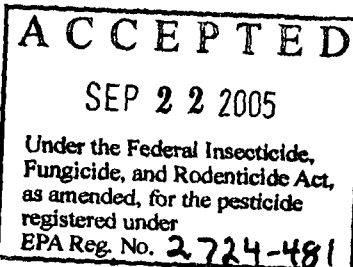
REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

NET CONTENTS

Lot No.

EPA Reg. No. 2724-481

EPA Est. No.



DATA PACKAGE BEAN SHEET

Date: 31-May-2005

Page 1 of 1

FEE

234
#18259

*** Registration Information ***

Registration: 2724-481 - TAU-FLUALINATE TECHNICAL

Company: 2724 - WELLMARK INTERNATIONAL

Risk Manager: RM 03 - Richard Gebken - (703) 305-6701 Room# CM-2 201

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: _____

Calculated Due Date: 06-Oct-2005

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R34) NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEMEN

Ingredients: 109302, Fluvalinate(87.2%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 31-May-2005

Due Back: _____

DP Ingredient: 109302, Fluvalinate

DP Title: change amnufacturing source

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 06-Sep-2005

Team Name: Chen

Science Due Date: 9-9-05

Reviewer Name: S.B. Mathew

7/28/05

8/4/05

Sub-Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

*** Additional Data Package for this Decision ***

*** Data Package Instructions ***

Please review the attached amendment to change the source of manufacturing.

Date: August 4, 2005

SUBJECT: Product Chemistry Review of Tau-Fluvalinate TGAI / MUP

FROM: Shyam B. Mathur, Ph.D
Product Chemistry Team Leader
Technical Review Branch/RD (7505C)

TO: Dana Pilitt / Richard Gebken, RM 03
Insecticide Branch / RD (7505C)

SB Mathur
8/04/05
DM

DP BARCODE: D317737

DECISION No.: 356215

File Symbol No.: 2724-481

PRODUCT: Tau-Fluvalinate TGAI / MUP

PCC: 109302

REGISTRANT: Wellmark International

USE: Insecticide

INTRODUCTION:

The registrant has submitted an application to amend the registration for the technical tau-fluvalinate. The registrant, Wellmark International intends to replace the current manufacturing source [REDACTED] with [REDACTED]. In support the registrant has submitted product chemistry data corresponding to 830 Series Subgroup A & Subgroup B under MRID Nos. 465278-01 thru 465278-04, the CSF for alternate formulation (dated 03-07-05) and the product label. The purity of the AI is increased from 87.2% to 93.72%, the revised product reflects the new purity of the AI. The impurity profile claimed on the alternate CSF [REDACTED] represents all of the impurities which potentially could be produced in the course of manufacture of the technical product. Some of the impurities claimed were not present in the [REDACTED] 5-batch analysis but were claimed in the 5-batch analysis supporting the current production site of [REDACTED] (MRID Nos. 41889702, 45598800, 45598801). The 5-batch analysis of the [REDACTED] showed fewer impurities, but found [REDACTED] new impurity which was not found with the current source of production. A [REDACTED] impurity is reported with [REDACTED] process but is not new, since it occurred at less than 0.1% in the current process (and was not required to be reported). TRB has been asked to evaluate the product chemistry data submitted for TGAI/MUP.

SUMMARY OF FINDINGS:

1. The registrant has submitted a Confidential Statement of Formula for basic formulation (dated 03-07-05) for the proposed Tau-fluvalinate TGAI / MUP. The average purity of the technical / MUP is 93.72%, as determined by the five batch analysis. The proposed certified limits for the AI are in accordance with standard limits as described in 40CFR§158.175(b)(2) and the upper certified limits of the impurities are based on the five batch analysis. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively [MRID No. 465278-01 & 465278-03].
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160 [MRID No. 465278-03].

Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Quality control process information may be entitled to confidential treatment

BARCODE: D317737; **Reg. No. :** 2724-481 **PRODUCT:** Tau-FluvalinateTGAI/MUP

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.162. The active ingredient was produced by a three step integrated batch process. The details of the production process have been provided which included the amounts of each starting material used in the process, description of the equipment used, the reaction conditions (temperature, pH, etc.) and the yields of the final product and the steps taken to control the quality of the product [MRID No. 465278-03].

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.167. The registrant has listed [REDACTED] impurities present at the level of $\geq 0.1\%$ and were identified during five batch analysis, the mechanism of formation of each of the impurities listed on the alternate CSF have been provided. There are listed [REDACTED] new impurities which are not present in the basic formulation CSF (dated 5-22-91). The registrant has provided justifications & arguments to demonstrate that these [REDACTED] impurities are not of toxicological significance. The registrant has also stated that nitrosamine contaminants are not likely to be produced during the manufacture or generated in the finished product [MRID No. 465278-03].

5. The data submitted corresponding the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.170. The study was conducted under GLP requirements in compliance with 40CFR§160. Five representative batches of the Tau-Fluvalinate technical were analyzed for percent active ingredient by HPLC / UV (254 nm) using an external standardization method. [REDACTED]

[REDACTED] The analytical method was validated for accuracy, linearity, and precision. The LOD, and LOQ for the AI and each impurity were determined [MRID No. 465278-04].

6. The data submitted corresponding to the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The active ingredient tau-fluvalinate content was determined by HPLC/UV (254 nm) using an external standardization method [MRID No. 465278-04].

7. The data submitted [830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.7000, 830.7100 and 830.7300] corresponding to guidelines 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190. These data have been submitted in response to Agency's letter dated October 29, 2003. The data for one year storage stability (830.6317) and corrosion characteristics (830.6320) studies were submitted previously under MRID No. 46109301 and were found acceptable (see PCR dated 03-08-04, D298105) by Agency [MRID No. 465278-02].

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for tau-fluvalinate TGAI / MUP and has concluded that:

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.
2. The CSF for alternate formulation (dated 03-07-05) is acceptable. However, the acceptance is subject to the evaluation of toxicity of the new impurity identified in the new manufacturing site. The registrant has provided arguments indicating that the new impurity is not of toxic concern. TRB recommends that the data should be forwarded to HED for further evaluation.
3. The data submitted corresponding to the 830 Series Subgroup B (physical-chemical properties) are acceptable.

BARCODE: D317737; **Reg. No. :** 2724-481 **PRODUCT:** Tau-FluvalinateTGAI/MUP

830.1550. Product identity & Composition: (MRID No. 465278-03)

Common Name: Tau-Fluvalinate

Chemical Name (CAS): cyano(3-phenoxyphenyl)methyl N-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate

Chemical Name (IUPAC): (RS)- α -cyano-3-phenoxybenzyl N-(2-chloro- α , α , α -trifluoro-p-tolyl)-D-valinate

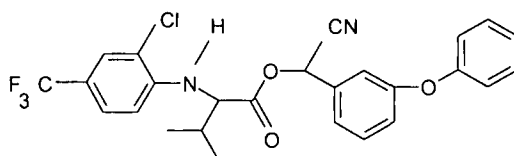
CAS No.: 102851-06-9

PC Code No.: 109302

Empirical formula: $C_{26}H_{22}ClF_3N_2O_3$

Molecular Weight: 502.9

Structural formula:



Tau-Fluvalinate

BARCODE: D317737; Reg. No. : 2724-481 PRODUCT: Tau-FluvalinateTGAI/MUP

Table 1. Manufacturing and Impurity Data for Tau-Fluvalinate technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	Alternate CSF dated (03-07-05)	A	The NC of AI (93.72%) is supported by 5 batch analysis & agrees with the label claim NC. [REDACTED] impurities ($\geq 0.1\%$) are listed on the CSF.
830.1600	Description of materials used to produce the product	465278-03	A	The product specification sheets (MSDS) for all the starting materials have been provided by the registrant
830.1620	Description of production process	465278-03	A	The AI was produced in three step integrated batch process. The production process has been described in full details. The reaction conditions, amounts of chemicals in each step, duration of time, and the yields in each step have been provided. The QA steps involved in each step have been described.
830.1670	Discussion of formation of impurities	465278-03	A	The registrant has provided the complete mechanisms of formation, quantification and identification of all the impurities present at the levels of $\geq 0.1\%$. Total number of impurities listed on the alternate CSF are less than those on basic CSF. [REDACTED] new impurity has been reported which was not listed on basic CSF. According to registrant it is of no toxic concern, also there are very low possibilities of the formation of nitrosamine during the synthesis, if at all present the level will be < 1 ppm.
830.1700	Preliminary analysis	465278-04	A	The registrant has provided 5 batch analysis for the TGAi. The content of AI was determined by HPLC/UV (254 nm) and the impurities were identified and quantified by using GC-FID internal standard methods. The methods were validated for accuracy, linearity, and precision. The LOQ and LOD for the AI & each impurity have been determined. The five batch analysis supported the CSF for alternate formulation.
830.1750	Certified limits	465278-01	A	The proposed certified limits for the AI are based on the standard certified limits table in 40CFR§158.175(b)(2). The certified limits for the impurities are based on the analytical results.
830.1800	Enforcement analytical method	465278-04	A	The HPLC/UV (254 nm) method was used for the determination of the AI content in the TGAi/MUP by using external standard.
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

BARCODE: D317737; Reg. No. : 2724-481 PRODUCT: Tau-Fluvalinate TGAI/MUP

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of Tau-Fluvalinate technical				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	C o l o r	465278-02	A	Clear, transparent, amber
830.6303	Physical state	" " "	A	Viscous liquid
830.6304	Odor	" " "	A	Slight, sour-sweet
830.6313	Stability to normal and elevated temperatures, metals, and metal ions			Previously accepted
830.6314	Oxidation/reduction: chemical incompatibility	465278-02	A	Compatible with oxidizing & reducing agents, water, iron powder, & water
830.6315	Flammability	465278-02	A	> 110°C
830.6316	Explosibility	465278-02	A	Not potentially explosive
830.6317	Storage stability	461093-01	A	Accepted in previous submission
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics	461093-01	A	Accepted in previous submission
830.7000	pH	465278-02	A	5.31 at 25°C
830.7050	UV/Visible absorption		W	Waived in previously
830.7100	Viscosity	464755-03	Y	205600 mPa.s (cp) at 23°C;
830.7200	Melting point		NA	
830.7220	Boiling point	Cited		> 450°C (from literature)
830.7300	Relative Density	465278-02	A	1.2746 @ 25 °C
830.7370	Dissociation constants in water			
830.7550	Partition coefficient	cited		Ko/w = 7000 (from literature)
830.7840	Water solubility:	cited		0.002 mg/kg (in water); freely soluble in organic solvents (from literature)
830.7950	Vapor pressure	cited		< 0.013 m Pa (25°C) (from literature)

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Upgrade (additional information required)

BARCODE: D317737; **Reg. No. :** 2724-481 **PRODUCT:** Tau-Fluvalinate TGAI/MUP

830.1800. Enforcement of analytical method: (MRID No. 465278-02)

The active ingredient content in tau-fluvalinate technical was determined by HPLC/UV with external standard technique.

Apparatus: A suitable HPLC machine

Column: Purospher STAR RP-18e, 150 mm x 4.6 mm (id), 5.0 µm film thickness

Injection volume: 10µL

Oven temperature: 40°C

Detector: DAD operating at 254 nm

Solvent elution pattern:

Time (min)	Water (%)	Acetonitrile (%)	MeOH (%)	Flow (ml/min)
0-16	20	40	40	1
18-23	5	47.5	47.5	1
25	20	40	40	1

Retention time for tau-fluvalinate is about 15.2 -15.5 min

Pages 12-29 *Confidential Appendix May be Subject to Confidential Treatment*



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-481	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/tau-Fluvalinate Technical	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 E. Woodfield Rd., Suite 200 W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Application to change source of manufacturing. PRIA Fee for Service = R34 Amendment to a Registration. 5-monthreview, \$3,000.
gary.sandberg@wellmarkint.com

Section - III

1. Material This Product Will be Packaged In:			2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packagin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted If "Yes" Unit Packaging wgt. No. per container If "Yes" Unit Packaging wgt. No. per container				
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 245 kg./ 540 lbs..		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Gary R. Sandberg	Title Federal Regulatory Project Manager	Telephone No. (Include Area Code) (847) 330-5379
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Federal Regulatory Project Manager	
4. Typed Name Gary R. Sandberg	5. Date 15 April, 2005	

DP BARCODE No.: D321133 **REG. No.:** 2724-481 **PRODUCT NAME:** Tau-Fluvalinate Technical

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for 830 series Subgroup B and has concluded that:

1. The data submitted corresponding to guideline 830.7220 (boiling point) satisfy the data requirements of 40CFR158.190 and is acceptable.
2. The data submitted corresponding to guideline 830.7050 (UV/VIS) satisfy the data requirements of 40CFR158.190 and is acceptable.

Wellmark

June 16, 2005

Document Processing Desk
Registration Division
Office of Pesticide Programs (7505C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

Attention: G. LaRocca

**Subject: Tau-Fluvalinate Technical
EPA Reg. No. 2724-481
[REDACTED] Supporting Data**

Dear Mr. LaRocca:

On April 15, 2005, Wellmark submitted an application to the Agency to change the manufacturing source of tau-fluvalinate to [REDACTED]. Based on the acceptability of certain product chemistry studies conducted with PAI and previously found acceptable by the Agency, I cited four studies to support this change in my letter to you dated April 26, 2005. The studies were:

1. 63-8 / 830.7860 -Solubility. MRID 44694101
2. 63-9 / 830.7950 - Vapor Pressure. MRID 44694101
3. 63-10 / 830.7370 -Dissociation Constant. MRID 41597201
4. 63-11 / 830.7550 - Octanol/Water Partition Coefficient. MRID 44694101

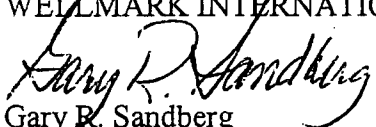
It was also determined at that time that 2 new studies were required to support the new [REDACTED] source. These studies are submitted in one report with this correspondence:

1. 63-3 / 830.7220 - Boiling Point. The test substance used for this study was the TGA1 from the [REDACTED] source.
2. 830.7050 - UV / Visible Absorption. Wellmark did not have this study on file to support the previous source of tau-fluvalinate. A new study was completed with the [REDACTED] PAI.

Product ingredient source information may be entitled to confidential treatment

This submission fulfills all study requirements that were identified to support our application for approval of a new source of manufacturing for technical Tau-fluvalinate (EPA Reg. No. 2724-481). Please call if you have any questions or need additional information.

Sincerely,
WELLMARK INTERNATIONAL


Gary R. Sandberg
Federal Regulatory Project Manager
(847) 330-5379
gary.sandberg@wellmarkint.com

cc: Ms. Kylie Rothwell (Special Review and Reregistration Division)


Product ingredient source information may be entitled to confidential treatment

Pending New label

TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Tau-fluvalinate (CAS #102851-06-9) 93.7%

Deleted: 87.2

OTHER INGREDIENTS: 6.3%

Deleted: 12.8

TOTAL 100.0%

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA
REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

NET CONTENTS

Lot No.

EPA Reg. No. 2724-481

EPA Est. No.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-248-7763 for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

Avoid hand - or sleeve-to-face exposure. Only for formulation into an insecticide for the following use(s): (1) other manufacturing use products, turf, indoor plants (including greenhouses) and outdoor ornamental plantings and landscapes, trees, shrubs, flower and foliage cuttings, containerized nursery stock, and on outside surfaces and around buildings; (2) uses for which US Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with US Environmental Protection Agency requirements.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding support of such uses.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food, or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of tau-fluvalinate technical may be disposed of on site or at any approved waste disposal facility.

CONTAINER DISPOSAL (Metal): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

WARRANTY AND CONDITIONS OF SALE

Seller warrants that the chemical composition of this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. Seller makes no other warranty, express or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given on the label.

For information or in case of an emergency, call 1-800-248-7763

Wellmark International
Schaumburg, IL 60173
Made in USA

PREVIOUS LABEL

TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Tau-fluvalinate (CAS #102851-06-9) 87.2%

OTHER INGREDIENTS: 12.8%

TOTAL 100.0%

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA
REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

NET CONTENTS

Lot No.

EPA Reg. No. 2724-481

EPA Est. No.

ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN 13 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

2724-481

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand- or sleeve-to-face exposure.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-248-7763 for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

Only for formulation into an insecticide for the following use(s): (1) other manufacturing use products, turf, indoor plants (including greenhouses) and outdoor ornamental plantings and landscapes, trees, shrubs, flower and foliage cuttings, containerized nursery stock, and on outside surfaces and around buildings; (2) uses for which US Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with US Environmental Protection Agency requirements.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding support of such uses.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture, or registration of any products without prior written authorization from Wellmark International.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food, or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of tau-fluvalinate technical may be disposed of on site or at any approved waste disposal facility.

CONTAINER DISPOSAL (Metal): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

WARRANTY AND CONDITIONS OF SALE

Seller warrants that the chemical composition of this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. Seller makes no other warranty, express or implied, concerning the use of this product other than as indicated on the label.

Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given on the label.

For information or in case of an emergency, call 1-800-248-7763

Wellmark International
Schaumburg, IL 60173
Made in USA

Fee for Service

This package includes the following

☐ New Registration

☒ Amendment

☐ Waiver Request and type

☐ 100% ☐ 50% ☐ IR-4 ☐ Minor ☐ Fed/state

for Division

☒ RD

☐ AD

☐ BPPD

Risk Mgr.

3

Receipt Nos. S-

777 617

EPA File Symbol/Reg. No.

2724 - 481

Pin-Punch Date:

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R34

Granted:

R34

Amount due: \$

3000⁰⁰

Parent/Child Decisions:

☐ Voluntary Payment Request

% Reduction

Reviewer:

[Signature]

Date:

4/20/05

Remarks:

(use back if needed)

ok - LUK



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 Wellmark International, 1501 E. Woodfield Rd., Schaumburg, IL 60173

EPA Registration Number/File Symbol
 2724-481

Active Ingredient(s) and/or representative test compound(s)
 Tau-fluvalinate Technical

Date
 15 April, 2005

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 Turf, indoor plants, greenhouses, outdoor ornamental, landscapes, nursery stock, apiary.

Product Name
 Tau-fluvalinate Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

Gary R. Sandberg

Date

15 April, 2005

Typed or Printed Name and Title

Gary R. Sandberg, Regul. Project Manager



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 15 April, 2005			EPA Reg No./File Symbol 2724-481		Page 1 of 1
Applicant's/Registrant's Name & Address Wellmark International, 1501 E. Woodfield Rd., Suite 200 W, Schaumburg, ILL 60173			Product Tau-fluvalinate Technical		
Ingredient Tau-fluvalinate					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition		Wellmark International	PER	
830.1600	Description of materials used to produce		Wellmark International	PER	
830.1620	Description of productin process		Wellmark International	PER	
830.1670	Discussion of formation of impurities		Wellmark International	PER	
830.1700	Preliminary analysis		Wellmark International	PER	
830.1750	Certificate of analysis (CSF)		Wellmark International	PER	
830.1800	Enforcement analytical method		Wellmark International	PER	
830.6302	Color		Wellmark International	PER	
830.6303	Physical state		Wellmark International	PER	
830.6304	Odor		Wellmark International	PER	
830.6314	Oxidation / Reduction		Wellmark International	PER	
830.6315	Flammability		Wellmark International	PER	
830.6316	Explodeability		Wellmark International	PER	
830.7000	pH		Wellmark International	PER	
830.7100/7300	Viscosity / Bulk density		Wellmark International	PER	
Signature <i>Gary R. Sandberg</i>			Name and Title Gary R. Sandberg, Federal Regulatory Project Manager		Date 15 April, 2005

APR 18 2005

AMEND

2724-481



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 20, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 18-APR-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MEMORANDUM

DATE: 4/21/05

TO: George LaRocca (13), Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

G. LAROCCA

4-22-05

PM 3

FEE FOR SERVICE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 20, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-356215
EPA File Symbol or Registration Number: 2724-481
Product Name: TAU-FLUALINATE TECHNICAL
EPA Receipt Date: 18-Apr-2005
EPA Company Number: 2724
Company Name: WELLMARK INTERNATIONAL

GARY R. SANDBERG
WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R34

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

Please remit payment in the amount of: \$ 3,000 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

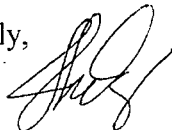
Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,



Front End Processing Staff
Information Resources and Services Division

Wellmark

June 16, 2005

Document Processing Desk
Registration Division
Office of Pesticide Programs (7505C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

Attention: G. LaRocca

Subject: Tau-Fluvalinate Technical
EPA Reg. No. 2724-481
[REDACTED] Supporting Data

Dear Mr. LaRocca:

On April 15, 2005, Wellmark submitted an application to the Agency to change the manufacturing source of tau-fluvalinate to [REDACTED]. Based on the acceptability of certain product chemistry studies conducted with PAI and previously found acceptable by the Agency, I cited four studies to support this change in my letter to you dated April 26, 2005. The studies were:

1. 63-8 / 830.7860 -Solubility. MRID 44694101
2. 63-9 / 830.7950 - Vapor Pressure. MRID 44694101
3. 63-10 / 830.7370 -Dissociation Constant. MRID 41597201
4. 63-11 / 830.7550 - Octanol/Water Partition Coefficient. MRID 44694101

It was also determined at that time that 2 new studies were required to support the new [REDACTED] source. These studies are submitted in one report with this correspondence:

1. 63-3 / 830.7220 - Boiling Point. The test substance used for this study was the TGAI from the [REDACTED] source.
2. 830.7050 - UV / Visible Absorption. Wellmark did not have this study on file to support the previous source of tau-fluvalinate. A new study was completed with the [REDACTED] PAI.

Product ingredient source information may be entitled to confidential treatment

This submission fulfills all study requirements that were identified to support our application for approval of a new source of manufacturing for technical Tau-fluvalinate (EPA Reg. No. 2724-481). Please call if you have any questions or need additional information.

Sincerely,
WELLMARK INTERNATIONAL



Gary R. Sandberg
Federal Regulatory Project Manager
(847) 330-5379
gary.sandberg@wellmarkint.com

cc: Ms. Kylie Rothwell (Special Review and Reregistration Division)



Product ingredient source information may be entitled to confidential treatment

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER:

Wellmark International
1501 East Woodfield Road
Suite 200 West
Schaumburg, Illinois 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION:

Submission of Product Chemistry data in support of the tau-fluvalinate reregistration.

3. TRANSMITTAL DATE: June 16, 2005

4. LIST OF DOCUMENTS SUBMITTED:

46573801 Vol. 1. Sinning, D.J. (2005) Physical and Chemical Characteristics of Tau Fluvalinate Technical: UV/Visible Absorption and Boiling Point. Sponsor: Makhteshim-Agan of North America, Inc., testing facility: Case Consulting Laboratories, Inc. Study Number 1820-58. May 19, 2005, 14p.

COMPANY NAME: Wellmark International

COMPANY AGENT: Gary R. Sandberg
Federal Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

AGENT SIGNATURE:



DATE: June 16, 2005

COMPANY CONTACT: Gary R. Sandberg **PHONE:** (847) 330-5379

Decision Seq. 359746

Action Code: 305,DATA REQUIRED;TECHNICAL;190

...

FFS Start Date

Tentative Ind: No

FFS Original Decision:

...

Due Date 24-Dec-2005

FFS EUP Decision:

...

OPP Target Due Dt:

FFS Sect3 Decision:

...

Negotiated Due Dt:

Start/Stop Clock

FQPA Clock:

Registrant

Response Due Date:

Days Elapsed:

Current Status: PENDING (16-Aug-2005)

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Decision Comments

Meetings & Milestones

FFS Information

FFS Negotiated Due Dates

OPP Target Due Date

Decision Ownership

Receipts

Data Package

Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 780438	Pillitt, Dana	2724-481	24-Dec-2005	PENDING
Submit boiling point and UV/Visible absorption data.				

Viewing Record 1 of 1

MEMORANDUMDATE: 6/20/05TO: George Lakooa (13), Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 17, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 17-JUN-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Reg Number: 2724-481 Reg. Type: Product Registration - Section 3 Status: Conditionally Registered (02-Jan-1
 Name: TAU-FLUALINATE TECHNICAL <View Registration Details>

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
----	-----------------	----------------	--------------	-------------

- ...Decisions...
- D: 356215; 2724-481; R34; NON-FAST-TRAC
 - S: 779302 4/27/05; Amendment; 2724
 - S: 777617 4/18/05; Amendment; 2724
 - D: 336502; 2724-481; 345; FORMULA CHANG
 - D: 330203; 2724-481; 300; LABEL REVISION; N
 - D: 192336; 2724-481; 350; GENERAL CORRE
 - D: 192335; 2724-481; 345; FORMULA CHANG
 - D: 192334; 2724-481; 300; LABEL REVISION; N
 - D: 192333; 2724-481; 345; FORMULA CHANG
 - D: 192332; 2724-481; 405; ADVERSE DATA (6
 - D: 192331; 2724-481; 300; LABEL REVISION; N
 - D: 192330; 2724-481; 300; LABEL REVISION; N
 - D: 192329; 2724-481; 300; LABEL REVISION; N
 - D: 192328; 2724-481; 300; LABEL REVISION; N
 - D: 192327; 2724-481; 300; LABEL REVISION; N
 - D: 192326; 2724-481; 300; LABEL REVISION; N
 - D: 192325; 2724-481; 300; LABEL REVISION; N
 - D: 192324; 2724-481; 300; LABEL REVISION; N

S: 779302 Reg #: 2724-481

Submission Type: Amendment

Resubmission?: ☒ Yes ☐ No

Decision #: 356215; R34; NON-FAST-TRACK (INCLUDES CHANGES TO P

Submitter Company: WELLMARK INTERNATIONAL

Application Date: 26-Apr-2005

OPP Received Date: 27-Apr-2005 Date Sent to Risk manager: 03-May-2005

Studies Included?: ☐ Yes ☒ No Fast Track?: ☐ Yes ☒ No

Form A Signed?: ☐ Yes ☐ No ☒ None Date:

Form B Signed?: ☐ Yes ☐ No ☒ None Date:

Reviewer: Pillitt, Dana

Received DT: Editable Due DT:

Submission Due DT: 06-Oct-2005 Response: 0, 27-Apr-2005

Priority Weight: Priority Points:

Wellmark

April 26, 2005

Document Processing Desk
Registration Division
Office of Pesticide Programs (7505C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

Attention: G. LaRocca

Subject: Tau-Fluvalinate Technical
EPA Reg. No. 2724-481
[REDACTED] Supporting Data

Dear Mr. LaRocca:

As a follow up to our conversations by e-mail last week, it was agreed that certain product chemistry studies conducted with PAI and accepted by the Agency can be cited in support of a new source of active ingredient. Accordingly, Wellmark International is citing 4 studies to support the recently submitted change of manufacturing source for tau-fluvalinate technical to [REDACTED]. These studies are currently approved by the Agency:

1. 63-8 / 830.7860 -Solubility.

MRID 44694101 Seymour, D. and A.P. Clark (1998) Physical and Chemical Properties Tests for tau-Fluvalinate. Midwest Research Institute, Project 4851-01, Wellmark Study 2516, October 7, 1998, 39p.
-EPA correspondence May 21, 2001: Acceptable.
-EPA Guideline Status Report dated April 16, 2003: Acceptable.

2. 63-9 / 830.7950 - Vapor Pressure.

MRID 44694101 Seymour, D. and A.P. Clark (1998) Physical and Chemical Properties Tests for tau-Fluvalinate. Midwest Research Institute, Project 4851-01, Wellmark Study 2516, October 7, 1998, 39p.
-EPA correspondence May 21, 2001: Acceptable.
-EPA Guideline Status Report dated April 16, 2003: Acceptable.

Product ingredient source information may be entitled to confidential treatment

3. 63-10 / 830.7370 -Dissociation Constant.

MRID 41597201 Apodaca, C. (1990) Determination of the Dissociation Constant of Fluvalinate. Sandoz Crop Protection Corp. Project 480603-1, April 30, 1990, 27p.
-EPA correspondence October 11, 1995: Acceptable.
-EPA Guideline Status Report dated April 16, 2003: Acceptable.

4. 63-11 / 830.7550 - Octanol/Water Partition Coefficient.

MRID 44694101 Seymour, D. and A.P. Clark (1998) Physical and Chemical Properties Tests for tau-Fluvalinate. Midwest Research Institute, Project 4851-01, Wellmark Study 2516, October 7, 1998, 39p.
-EPA correspondence May 21, 2001: Acceptable.
-EPA Guideline Status Report dated April 16, 2003: Acceptable.

It was also determined that 2 new studies will be required to support the new [REDACTED] source. Preparations to complete these studies have begun and we anticipate they will be completed before the review process for the new source is completed. I will submit these studies as soon as they are completed. The studies to be completed are:

5. 63-3 / 830.7220 – Boiling Point.

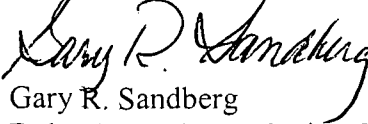
The test substance to be used for this study is the TGAI from the [REDACTED] source.

6. 830.7050 – UV / Visible Absorption.

Wellmark does not have this study on file to support the current source of tau-fluvalinate. A new study will be completed with the [REDACTED].

Please call if you have any questions or need additional information.

Sincerely,
WELLMARK INTERNATIONAL


Gary R. Sandberg
Federal Regulatory Project Manager
(847) 330-5379
gary.sandberg@wellmarkint.com

cc: Ms. Kylie Rothwell (Special Review and Reregistration Division)
[REDACTED]

305

Receipt for Section 3

S: 780438		Regulatory Type: Product Registration - Section 3		Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No		Print Letter	
Application Type: Amendment		Fee For Service: <input type="radio"/> Yes <input checked="" type="radio"/> No				Enter More Information	
Company: 2724		WELLMARK INTERNATIONAL		V			
Risk Manager: Registration Division, Risk Management Team 213							
Product #: 2724-481		Product Name: TAU-FLUALINATE TECHNICAL					
Override#:							
Me Too Section3:		Me Too Product Name:					
Application Date: 16-Jun-2005		iD		OPP Rec'd Date: 17-Jun-2005		iD	
Front End Date: 17-Jun-2005		iD		Risk Manager Send Date: 17-Jun-2005		iD	
FFS Due Date:				Negotiated Due Date:			
OPP Target Date:							
Fast Track: <input type="checkbox"/>		New Ingredient: <input type="checkbox"/>				Receipt Content	
Receipt Description:		product chemistry data, submit boiling point and UV/Visible absorption data		New Ingredient Request Date:		Study	
Form A: <input type="checkbox"/>		Signature Date:		Form B: <input type="checkbox"/>		Received Date:	

DD - 305 - Chem

Wellmark

June 16, 2005

Document Processing Desk
Registration Division
Office of Pesticide Programs (7505C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

Attention: G. LaRocca

Subject: Tau-Fluvalinate Technical
EPA Reg. No. 2724-481
[REDACTED] Supporting Data

Dear Mr. LaRocca:

On April 15, 2005, Wellmark submitted an application to the Agency to change the manufacturing source of tau-fluvalinate to [REDACTED]. Based on the acceptability of certain product chemistry studies conducted with PAI and previously found acceptable by the Agency, I cited four studies to support this change in my letter to you dated April 26, 2005. The studies were:

1. 63-8 / 830.7860 - Solubility. MRID 44694101
2. 63-9 / 830.7950 - Vapor Pressure. MRID 44694101
3. 63-10 / 830.7370 - Dissociation Constant. MRID 41597201
4. 63-11 / 830.7550 - Octanol/Water Partition Coefficient. MRID 44694101

It was also determined at that time that 2 new studies were required to support the new [REDACTED] source. These studies are submitted in one report with this correspondence:

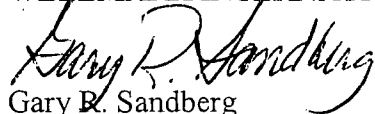
1. 63-3 / 830.7220 - Boiling Point. The test substance used for this study was the TGAI from the [REDACTED] source.
2. 830.7050 - UV / Visible Absorption. Wellmark did not have this study on file to support the previous source of tau-fluvalinate. A new study was completed with the [REDACTED] PAI.

Product ingredient source information may be entitled to confidential treatment

This submission fulfills all study requirements that were identified to support our application for approval of a new source of manufacturing for technical Tau-fluvalinate (EPA Reg. No. 2724-481). Please call if you have any questions or need additional information.

Sincerely,

WELLMARK INTERNATIONAL



Gary R. Sandberg

Federal Regulatory Project Manager

(847) 330-5379

gary.sandberg@wellmarkint.com

cc: Ms. Kylie Rothwell (Special Review and Reregistration Division)



Product ingredient source information may be entitled to confidential treatment

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER:

Wellmark International
1501 East Woodfield Road
Suite 200 West
Schaumburg, Illinois 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION:

Submission of Product Chemistry data in support of the tau-fluvalinate reregistration.

3. TRANSMITTAL DATE: June 16, 2005

4. LIST OF DOCUMENTS SUBMITTED:

46573801 Vol. 1. Sinning, D.J. (2005) Physical and Chemical Characteristics of Tau Fluvalinate Technical: UV/Visible Absorption and Boiling Point. Sponsor: Makhteshim-Agan of North America, Inc., testing facility: Case Consulting Laboratories, Inc. Study Number 1820-58. May 19, 2005, 14p.

COMPANY NAME: Wellmark International

COMPANY AGENT: Gary R. Sandberg
Federal Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

AGENT SIGNATURE:



DATE: June 16, 2005

COMPANY CONTACT: Gary R. Sandberg **PHONE:** (847) 330-5379

Explore Registrations

Reg Number: 2724-481 Reg. Type: Product Registration - Section 3 Status: Conditionally Registered (02-Jan-1
 Name: TAU-FLUALINATE TECHNICAL <View Registration Details>

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
----	-----------------	----------------	--------------	-------------

- ...Decisions...
- D: 356215; 2724-481; R34; NON-FAST-TRAC
 - S: 777617 4/18/05; Amendment; 2724
 - D: 336502; 2724-481; 345; FORMULA CHANG
 - D: 330203; 2724-481; 300; LABEL REVISION; P
 - D: 192336; 2724-481; 350; GENERAL CORRE
 - D: 192335; 2724-481; 345; FORMULA CHANG
 - D: 192334; 2724-481; 300; LABEL REVISION; P
 - D: 192333; 2724-481; 345; FORMULA CHANG
 - D: 192332; 2724-481; 405; ADVERSE DATA (6
 - D: 192331; 2724-481; 300; LABEL REVISION; P
 - D: 192330; 2724-481; 300; LABEL REVISION; P
 - D: 192329; 2724-481; 300; LABEL REVISION; P
 - D: 192328; 2724-481; 300; LABEL REVISION; P
 - D: 192327; 2724-481; 300; LABEL REVISION; P
 - D: 192326; 2724-481; 300; LABEL REVISION; P
 - D: 192325; 2724-481; 300; LABEL REVISION; P
 - D: 192324; 2724-481; 300; LABEL REVISION; P
 - D: 192323; 2724-481; 300; LABEL REVISION; P
 - D: 192322; 2724-481; 300; LABEL REVISION; P
 - D: 192321; 2724-481; 300; LABEL REVISION; P

S: 777617 Reg #: 2724-481

Submission Type: Amendment

Resubmission?: ☐ Yes ☒ No

Decision #: 356215; R34; NON-FAST-TRACK (INCLUDES CHANGES TO P

Submitter Company: WELLMARK INTERNATIONAL

Application Date: 15-Apr-2005

OPP Received Date: 18-Apr-2005

Date Sent to Risk manager: 20-Apr-2005

Studies Included?: ☐ Yes ☒ No

Fast Track?: ☐ Yes ☒ No

Form A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☐ Yes ☐ No ☒ None

Date:

Reviewer: Pillitt, Dana

Received DT:

Editable Due DT:

Admin Due DT:

Response: 18-Apr-2005

Priority Weight:

Priority Points:

Comments: Amendment application to change source of manufacturing.

DATA PACKAGE BEAN SHEET

Date: 25-Aug-2005

Page 1 of 2

Decision #: 359746

DP #: (321133)

*** Registration Information ***

Registration: **2724-481 - TAU-FLUALINATE TECHNICAL**

Company: 2724 - WELLMARK INTERNATIONAL

Risk Manager: RM 03 - Richard Gebken - (703) 305-6701 Room# CM-2 201

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: 17-Jun-2005

Calculated Due Date: 24-Dec-2005

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (305) DATA REQUIRED; TECHNICAL;

Ingredients: 109302, Fluvalinate(87.2%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 25-Aug-2005

Due Back: _____

DP Ingredient: 109302, Fluvalinate

DP Title: Boiling point & UV/Visible absorption data

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 27-Jul-2005

Team Name: _____

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the attached boiling point and UV/Visible absorption data MRID 46573801 for the changed source material.

DP#: (321133)

*** Studies Sent for Review ***

Decision#: (359746)

MRID	Citation Reference	Guideline
46573801	Sinning, D. (2005) Physical and Chemical Characteristics of Tau-Fluvalinate Technical: UV/Visible Absorption and Boiling Point: Final Report. Project Number: 1820/58. Unpublished study prepared by Case Consulting Laboratories, Inc. 14 p.	830.7050/UV/Visible absorption
46573801	Sinning, D. (2005) Physical and Chemical Characteristics of Tau-Fluvalinate Technical: UV/Visible Absorption and Boiling Point: Final Report. Project Number: 1820/58. Unpublished study prepared by Case Consulting Laboratories, Inc. 14 p.	830.7220/Boiling point/boiling range

DATA PACKAGE BEAN SHEET

Date: 31-May-2005

Page 1 of 1

***** Registration Information *****

Registration: 2724-481 - TAU-FLUALINATE TECHNICAL

Company: 2724 - WELLMARK INTERNATIONAL

Risk Manager: RM 03 - Richard Gebken - (703) 305-6701 Room# CM-2 201

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: _____

Calculated Due Date: 06-Oct-2005

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R34) NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEMEN

Ingredients: 109302, Fluvalinate(87.2%)

***** Data Package Information *****Expedite: ☐ Yes ☒ No

Date Sent: 31-May-2005

Due Back: _____

DP Ingredient: 109302, Fluvalinate

DP Title: change amnufacturing source

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 06-Sep-2005

Team Name: _____

Science Due Date: _____

Reviewer Name: _____

Sub-Data Package Due Date: _____

Contractor Name: _____

***** Studies Sent for Review ********** Additional Data Package for this Decision ********** Data Package Instructions *****

Please review the attached amendment to change the source of manufacturing.

7-6-05
Please change
the AT % in
OPPIN SP
to 97.3 %

Receipt for Section 3			
S: 777617			
Regulatory Type:	Product Registration - Section 3	Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Application Type:	Amendment	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Company:	2724 WELLMARK INTERNATIONAL	<input checked="" type="checkbox"/>	
Risk Manager:	Registration Division, Risk Management Team 13		
Product #:	2724-481	Product Name:	TAU-FLUALINATE TECHNICAL
Override#:			
Me Too Section3:		Me Too Product Name:	
Application Date:	15-Apr-2005	OPP Rec'd Date:	18-Apr-2005
Front End Date:	19-Apr-2005	Risk Manager Send Date:	
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>
Receipt Description:		New Ingredient Request Date: New Ingredient Received Date: Signature Date:	
Amendment application to change source of manufacturing.		Signature Date: Signature Date:	
Form A:	<input type="checkbox"/>	Form B:	<input type="checkbox"/>

Receipt Content
 Study

Print Letter
 Enter More Information

OP - Chem

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER:

Wellmark International
1501 East Woodfield Road
Suite 200 West
Schaumburg, Illinois 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION:

Submission of data to support a change in manufacturing source.

3. TRANSMITTAL DATE: April 15, 2005

4. LIST OF DOCUMENTS SUBMITTED:

- 46527801** Vol. 1. Everich, R (2005) Tau-Fluvalinate Technical: Group A Product Properties-Certified Limits. Makhteshim Chemical Works Ltd, MCW Study No. MANA 05-03, March 28, 2005, 4+6p.
- 46527802** Vol. 2. Sinning, D.J. (2005) Physical and Chemical Characteristics of Tau-Fluvalinate Technical: Color, Physical State, Odor, Oxidation/Reduction, Flammability, Explodability, pH, Viscosity and Relative Density. Case Consulting Laboratories, Inc., Study No. 1820-56, March 9, 2005, 12p.
- 46527803** Vol. 3. Everich, R. (2005) Tau-Fluvalinate Technical: Group A Product Properties (Manufacturing and Methods). Makhteshim Chemical Works Ltd, MCW Study No. MANA 05-02/R-17935, March 28, 2005, 3+119p.
- 46527804** Vol. 4. Pisarev, V (2004) Tau-fluvalinate-Quantification of active ingredient and impurities present at or above 0.1% in technical tau-fluvalinate. Makhteshim Chemical Works, Ltd, MCW Study No. R-14754, September 14, 2004, 69p.

COMPANY NAME: Wellmark International

COMPANY AGENT: Gary R. Sandberg
Federal Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

AGENT SIGNATURE:  **DATE:** April 15, 2005

COMPANY CONTACT: Gary R. Sandberg **PHONE:** (847) 330-5379

TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Tau-fluvalinate (CAS #102851-06-9) 93.7%

OTHER INGREDIENTS: 6.3%

TOTAL 100.0%

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA

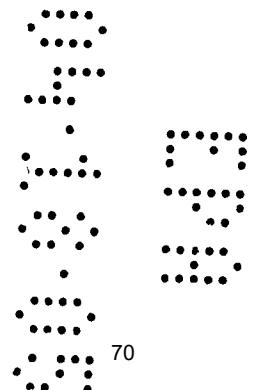
REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

NET CONTENTS

Lot No.

EPA Reg. No. 2724-481

EPA Est. No.



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-248-7763 for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

Avoid hand - or sleeve-to-face exposure. Only for formulation into an insecticide for the following use(s): (1) other manufacturing use products, turf, indoor plants (including greenhouses) and outdoor ornamental plantings and landscapes, trees, shrubs, flower and foliage cuttings, containerized nursery stock, and on outside surfaces and around buildings; (2) uses for which US Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with US Environmental Protection Agency requirements.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding support of such uses.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food, or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of tau-fluvalinate technical may be disposed of on site or at any approved waste disposal facility.

CONTAINER DISPOSAL (Metal): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

WARRANTY AND CONDITIONS OF SALE

Seller warrants that the chemical composition of this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. Seller makes no other warranty, express or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given on the label.

For information or in case of an emergency, call 1-800-248-7763

Wellmark International
Schaumburg, IL 60173
Made in USA



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-481	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/tau-Fluvalinate Technical	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 E. Woodfield Rd., Suite 200 W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Application to change source of manufacturing. PRIA Fee for Service = R34 Amendment to a Registration. 5-monthreview, \$3,000.
gary.sandberg@wellmarkint.com

Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packagin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be omitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Unit Packaging wgt. No. per container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 245 kg./ 540 lbs..		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Gary R. Sandberg	Title Federal Regulatory Project Manager	Telephone No. (Include Area Code) (847) 330-5379
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Federal Regulatory Project Manager	
4. Typed Name Gary R. Sandberg	5. Date 15 April, 2005	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 15 April, 2005	EPA Reg No./File Symbol 2724-481	Page 1 of 1
Applicant's/Registrant's Name & Address Wellmark International, 1501 E. Woodfield Rd., Suite 200 W, Schaumburg, ILL 60173		Product Tau-fluvalinate Technical

Ingredient Tau-fluvalinate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition		Wellmark International	PER	
830.1600	Description of materials used to produce		Wellmark International	PER	
830.1620	Description of productin process		Wellmark International	PER	
830.1670	Discussion of formation of impurities		Wellmark International	PER	
830.1700	Preliminary analysis		Wellmark International	PER	
830.1750	Certificate of analysis (CSF)		Wellmark International	PER	
830.1800	Enforcement analytical method		Wellmark International	PER	
830.6302	Color		Wellmark International	PER	
830.6303	Physical state		Wellmark International	PER	
830.6304	Odor		Wellmark International	PER	
830.6314	Oxidation / Reduction		Wellmark International	PER	
830.6315	Flammability		Wellmark International	PER	
830.6316	Explodeability		Wellmark International	PER	
830.7000	pH		Wellmark International	PER	
830.7100/7300	Viscosity / Bulk density		Wellmark International	PER	
Signature <i>Gary R. Sandberg</i>			Name and Title Gary R. Sandberg, Federal Regulatory Project Manager	Date 15 April, 2005	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 Wellmark International, 1501 E. Woodfield Rd., Schaumburg, IL 60173

EPA Registration Number/File Symbol
 2724-481

Active Ingredient(s) and/or representative test compound(s)
 Tau-fluvalinate Technical

Date
 15 April, 2005

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 Turf, indoor plants, greenhouses, outdoor ornamental, plantscapes, nursery stock, apiary.

Product Name
 Tau-fluvalinate Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Gary R. Sandberg

Date

15 April, 2005

Typed or Printed Name and Title

Gary R. Sandberg, Regul. Project Manager



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 15 April, 2005	EPA Reg No./File Symbol 2724-481	Page 1 of 1
Applicant's/Registrant's Name & Address Wellmark International, 1501 E. Woodfield Rd. Suite 200 W, Schaumburg, IL 60173		Product Tau-fluvalinate Technical

Ingredient Tau-fluvalinate

Submitter	Status	Note
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	
Wellmark International	PER	

Signature <i>Gary R. Sandberg</i>	Name and Title Gary R. Sandberg, Federal Regulatory Project Manager	Date 15 April, 2005
-----------------------------------	---	---------------------

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER:

Wellmark International
1501 East Woodfield Road
Suite 200 West
Schaumburg, Illinois 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION:

Submission of data to support a change in manufacturing source.

3. TRANSMITTAL DATE: April 15, 2005

4. LIST OF DOCUMENTS SUBMITTED:

Vol. 1. Everich, R (2005) Tau-Fluvalinate Technical: Group A Product Properties-Certified Limits. Makhteshim Chemical Works Ltd, MCW Study No. MANA 05-03, March 28, 2005, 4+6p.

Vol. 2. Sinning, D.J. (2005) Physical and Chemical Characteristics of Tau-Fluvalinate Technical: Color, Physical State, Odor, Oxidation/Reduction, Flammability, Explodability, pH, Viscosity and Relative Density. Case Consulting Laboratories, Inc., Study No. 1820-56, March 9, 2005, 12p.

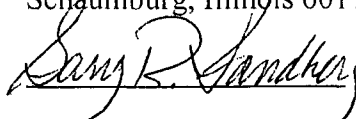
Vol. 3. Everich, R. (2005) Tau-Fluvalinate Technical: Group A Product Properties (Manufacturing and Methods). Makhteshim Chemical Works Ltd, MCW Study No. MANA 05-02/R-17935, March 28, 2005, 3+119p.

Vol. 4. Pisarev, V (2004) Tau-fluvalinate-Quantification of active ingredient and impurities present at or above 0.1% in technical tau-fluvalinate. Makhteshim Chemical Works, Ltd, MCW Study No. R-14754, September 14, 2004, 69p.

COMPANY NAME: Wellmark International

COMPANY AGENT: Gary R. Sandberg
Federal Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

AGENT SIGNATURE:



DATE: April 15, 2005

COMPANY CONTACT: Gary R. Sandberg **PHONE:** (847) 330-5379



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Jacket
10/15/12

April 20, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-356215
EPA File Symbol or Registration Number: 2724-481
Product Name: TAU-FLUALINATE TECHNICAL
EPA Receipt Date: 18-Apr-2005
EPA Company Number: 2724
Company Name: WELLMARK INTERNATIONAL

GARY R. SANDBERG
WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R34

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS; SOURCE CHANGES TO AN UNREGISTERED SOURCE);

Please remit payment in the amount of: \$ 3,000 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,



Front End Processing Staff
Information Resources and Services Division

Receipt for Section 3

S 777617

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☒ Yes ☐ No

Company: 2724 WELLMARK INTERNATIONAL



Risk Manager: Registration Division, Risk Management Team 3

Product #: 2724-481

Product Name: TAU-FLUALINATE TECHNICAL

Override#:

Me Too
Section 3:

Me Too
Product Name:

Application Date: 15-Apr-2005



OPP Rec'd Date: 18-Apr-2005



Front End Date: 19-Apr-2005



Risk Manager Send Date:



Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Amendment application to change source of manufacturing.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Receipt Content

Study



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 6 2004

Nancy Huebl
Regulatory Specialist
Wellmark International
1100 East Woodfield Road, Suite 500
Schaumburg, IL 60173

Subject: Product Chemistry Review for Storage Stability and Corrosion Characteristics
Tau-Fluvalinate Technical
EPA Registration No. 2724-481
Your submission dated October 31, 2003

Dear Ms. Huebl:

The Agency has reviewed the submitted study (MRID 46109301) and has determined that it satisfies the data requirements for storage stability (830-6317) and corrosion characteristics (830-6320)chnical. If you have any questions, please call Dr. William Sproat of my team at 703-308-8587.

Sincerely,

A handwritten signature in black ink, appearing to read "George T. LaRocca".

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

DATE OUT: 08 Mar 2004

SUBJECT: EP [] MP [x] PRODUCT CHEMISTRY REVIEW
DP BARCODE No.: D298105
REG./File Symbol No.: 2724-481
PRODUCT NAME: tau-Fluvalinate Technical
COMPANY: Wellmark International
FOOD USE: [] PC CODE: 109302
Decision No. 336502 Integrated Formulation [x]

TO: RM #03, Marion Johnson/William Sproat
Insecticide Branch
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505C)

Bruce F. Kitchens
08 Mar 2004 *SBR* *8/8/04*

INTRODUCTION:

The registrant, Wellmark International, is submitting product chemistry data to support the registered manufacturing use product, tau-Fluvalinate Technical. The active ingredient in this product is tau-Fluvalinate at a label nominal concentration of 87.2% a.i. This product is intended for use in the manufacture of insecticide end-use products. With this package, the registrant is submitting product chemistry data contained in MRID# 461093-01 to satisfy the data requirements for storage stability (830-6317) and corrosion characteristics (830-6320). The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. The registrant has submitted the following study entitled:

Wilkins, F.C., Storage Stability of tau-Fluvalinate Technical, Wellmark International, Project ID# N100, Study No. 2495.
2. The testing facility for this study was Wellmark International - Dallas Facility of Dallas, TX.

3. The registrant indicates that the study was conducted in compliance with Good Laboratory Practice (GLP) Standards as set forth in 40 CFR Part 160. This study was audited by the Quality Assurance Unit (QAU) of Wellmark International. The QAU of Wellmark did not describe the audited activity.
4. A brief description of the study follows:

This study was intended to determine the chemical and physical stability of aged tau-Fluvalinate Technical after storage at ambient warehouse storage conditions. The test system consisted of aged tau-Fluvalinate Technical and its commercial packaging, a closed head steel drum. Test samples were taken from the original container from lots that were stored at least one year or longer at ambient conditions. These lots were identified as Lot ID# 56512870, 56512970, B6712770, and B6813170. Lot ID# 56512870, 56512970, and B6712770 were analyzed after 16 months. Lot ID# B6813170 was analyzed after 21 months. Since there are no time zero samples, the registrant is using the label claim as the reference concentration (87.2% tau-Fluvalinate). The age of the samples will be calculated from the date of manufacture to the date of sampling. Active ingredient concentration was presented as a percent of the label claim. Samples were analyzed in replicate to control experimental bias. Samples were analyzed by High Pressure Liquid Chromatography (HPLC) under the following chromatographic conditions:

Instrument -	Hewlett-Packard 1090 HPLC equipped with heated column compartment, automatic sampler and injector
Column -	Hewlett-Packard Hypersil ODS 5um column, 200 x 4.6 mm
Oven Temp -	40°C
Detector -	UV Variable wavelength-diode array detector
Wavelength -	254 nm
Inject. Volume -	10 ul
Flow Rate -	1.8 ml/min
Mobile Phase -	Acetonitrile/Water 90:10 (degas with Helium)

DATA PACKAGE BEAN SHEET

Date: 21-Jan-2004

Page 1 of 1

***** Registration Information *****

Registration: 2724-481 - TAU-FLUALINATE TECHNICAL

Company: 2724 - WELLMARK INTERNATIONAL

Risk Manager: RM 03 - Marion Johnson - (703) 305-6788 Room# CM-2 219

Risk Manager Reviewer: William Sproat WSPROAT

Sent Date: 04-Nov-2003

Calculated Due Date: 29-Jan-2004

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (345) FORMULA CHANGE; TECHNICAL;

Ingredients: 109302, Fluvalinate(87.2%)

***** Data Package Information *****Expedite: ☐ Yes ☒ No

Date Sent: 21-Jan-2004

Due Back: _____

DP Ingredient: 109302, Fluvalinate

DP Title: storage stability data

CSF Included: ☐ Yes ☒ NoLabel Included: ☐ Yes ☒ No

Parent DP #: _____

Assigned To**Date In****Date Out**

Organization: RD / TRB

Administrative Due Date: 06-Mar-2004

Team Name: _____

Negotiated Due Date: _____

Reviewer Name: _____

Projected Completion Date: _____

Contractor Name: _____

***** Studies Sent for Review *****

No Studies

***** Additional Data Package for this Decision *****

No Additional Data Packages

***** Data Package Instructions *****

Please review the attached study, MRID 46109301, for storage stability, for EPA Reg No. 2724-481.

Thanks

Bill Sproat
308-8587

Reg Number: 2724-481 Reg. Type: Product Registration - Section 3 Status: Conditionally Registered (02-Jan-1
Name: TAU-FLUALINATE TECHNICAL <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description

...Decisions...

- D: 336502; 2724-481;345;FORMULA CHANG
- S: 749916 10/31/03, Amendment, 2724
- D: 330203; 2724-481;300;LABEL REVISION;P
- D: 192336; 2724-481;350;GENERAL CORRE
- D: 192335; 2724-481;345;FORMULA CHANG
- D: 192334; 2724-481;300;LABEL REVISION;P
- D: 192333; 2724-481;345;FORMULA CHANG
- D: 192332; 2724-481;405;ADVERSE DATA (6
- D: 192331; 2724-481;300;LABEL REVISION;P
- D: 192330; 2724-481;300;LABEL REVISION;P
- D: 192329; 2724-481;300;LABEL REVISION;P
- D: 192328; 2724-481;300;LABEL REVISION;P
- D: 192327; 2724-481;300;LABEL REVISION;P
- D: 192326; 2724-481;300;LABEL REVISION;P
- D: 192325; 2724-481;300;LABEL REVISION;P
- D: 192324; 2724-481;300;LABEL REVISION;P
- D: 192323; 2724-481;300;LABEL REVISION;P
- D: 192322; 2724-481;300;LABEL REVISION;P
- D: 192321; 2724-481;300;LABEL REVISION;P
- D: 192320; 2724-481;300;LABEL REVISION;P

S: 749916 Reg #: 2724-481

Submission Type: Amendment

Resubmission?: ☐ Yes ☒ No

Decision #: 336502; 345;FORMULA CHANGE;TECHNICAL;

Submitter Company: WELLMARK INTERNATIONAL

Application Date: 29-Oct-2003

OPP Received Date: 31-Oct-2003

Date Sent to Risk manager: 04-Nov-2003

Studies Included?: ☒ Yes ☐ NoFast Track?: ☒ Yes ☐ NoForm A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☐ Yes ☐ No ☒ None

Date:

Reviewer: Sproat, William

Received DT: 04-Nov-2003

Editable Due DT:

Admin Due DT: 29-Jan-2004

Response: 0, 24-Nov-2003

Priority Weight:

Priority Points:

Comments: Submission of storage stability data

345-WS

Receipt for Section 3			
S:	749916		
Regulatory Type:	Product Registration - Section 3	Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Application Type:	Amendment		
Company:	2724	WELLMARK INTERNATIONAL	<input checked="" type="checkbox"/>
Risk Manager:	Registration Division Risk Management Team 3		
Product #:	2724-481	Product Name:	TAU-FLUALINATE TECHNICAL
Override#:			
Me Too	Section 3:	Me Too	Product Name:
Application Date:	29-Oct-2003	OPP Rec'd Date:	31-Oct-2003
Front End Date:	04-Nov-2003	Risk Manager Send Date:	04-Nov-2003
Fast Track:	<input type="checkbox"/>	Studies:	<input checked="" type="checkbox"/>
		New ingredient:	<input type="checkbox"/>
Receipt Description:			
Submission of storage stability data			
New ingredient	Request Date:	New ingredient	Received Date:
Form A:	<input type="checkbox"/>	Signature Date:	
Form B:	<input type="checkbox"/>	Signature Date:	

Wellmark

October 29, 2003

Document Processing Desk
Registration Division
Office of Pesticide Programs (H7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: W. Sproat

Subject: Tau-fluvalinate Technical
EPA Reg. No. 2724-481
Storage Stability Study data requirement

Dear Dr. Sproat:

In anticipation of the Reregistration of Tau-fluvalinate, I am submitting the following information to insure that all Product Chemistry data requirements are addressed for this active ingredient. A copy of this correspondence has been sent to the Special Review and Reregistration Division for their records.

In the most recent OPP Guideline Status Report dated 04/16/03 for Tau-fluvalinate, the following data requirements were shown as unresolved. This correspondence is submitted to address those requirements:

63-15 / 830.6315 -Flammability.

Not required for TGAI (OPPTS 830.1000 Background for Product Properties Test Guidelines).

63-16 / 830.6316 - Explodability.

Not required for TGAI (OPPTS 830.1000 Background for Product Properties Test Guidelines).

63-17 / 830.6317 Storage Stability (shelf life)

Required. Three copies of the enclosed study with Transmittal Document are submitted to meet this data requirement.

63-18 / 830.7100 – Viscosity.

Not required for TGAI (OPPTS 830.1000 Background for Product Properties Test Guidelines).

63-19 / 830.6319 – Miscibility.

Not required for TGAI (OPPTS 830.1000 Background for Product Properties Test Guidelines).

63-20 / 830.6320 - Corrosion Characteristics.

Not required for TGAI (OPPTS 830.1000 Background for Product Properties Test Guidelines).

63-21 / 830.6321 - Dielectric breakdown voltage.

Not required for TGAI (OPPTS 830.1000 Background for Product Properties Test Guidelines).

830.7050 - UV / Visible absorption.

Waiver requested. Photo degradation studies have been submitted to the Agency or waivers granted for the following guideline requirements. MRID references by guideline are:

161-2, Photo degradation in Water – MRID 41597305, 45769203, 45769201 and 41597306.


161-3, Photo degradation on Soil – MRID 41597307, 45769201, 41597308 and 00083757.

161-4, Photo degradation in Air. Waiver granted by Agency.

The stability of Tau-fluvalinate under various light conditions has been well documented.

Please call if you have any questions or need additional information.

Sincerely,
WELLMARK INTERNATIONAL


Gary R. Sandberg
Federal Regulatory Project Manager
(847) 330-5379
gary.sandberg@wellmarkint.com

cc: K. Rothwell (SRRD)

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER:

Wellmark International
1100 East Woodfield Road
Suite 500
Schaumburg, Illinois 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION:

Submission of Study to support Reregistration of Tau-fluvalinate.

3. TRANSMITTAL DATE:

October 29, 2003

4. LIST OF DOCUMENTS SUBMITTED:

46109301 Vol. 1. Wilkins, FC (1998) Storage Stability of *tau*-Fluvalinate Technical (EPA Reg. No. 2724-481). Wellmark International Study 2495, November 11, 1998, 28p.

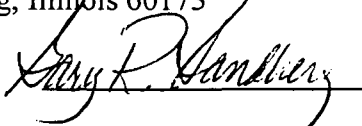
COMPANY NAME:

Wellmark International

COMPANY AGENT:

Gary R. Sandberg
Federal Regulatory Project Manager
Wellmark International
1100 East Woodfield Road, Suite 500
Schaumburg, Illinois 60173

AGENT SIGNATURE:



DATE: October 29, 2003

COMPANY CONTACT:

Gary R. Sandberg

PHONE:

(847) 330-5379

MEMORANDUM

DATE: 11/19/03

TO: Bruce Spilant (13), Regulatory Manager

FROM: Information Services Branch, IRSD

- Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

- We expect that it will be approximately two weeks from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 19, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WELLMARK INTERNATIONAL
1100 EAST WOODFIELD ROAD, SUITE 500
SCHAUMBURG, IL 60173

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 31-OCT-03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



United States
Environmental Protection Agency
 Office of Pesticide Programs (7505C)
 Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product
 2724-481

Distributor Company Number
 74054

Note: Do not submit distributor product labels

Name of Registered Product (*basic product name accepted by EPA*)
 Tau Fluvalinate Technical

Distributor Product Name
 Tau Fluvalinate Technical

Name and Address of Distributor (*Type; include ZIP code*)
 Invita Plant Protection N.V.
 c/o MANA, Inc.
 551 Fifth Avenue, Suite 1100
 New York, NY 10176

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Anne Stont Reg. Spec.

Date

10/6/03

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Nancy Shuehl Regulatory Specialist

Date

10/7/03



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 13 2004

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Nancy Huebl
Regulatory Specialist
Wellmark International
1100 East Woodfield Road, Suite 500
Schaumburg, IL 60173

Subject: Amendment - Revised First Aid and Disposal Statements
Tau-Fluvalinate Technical
EPA Registration No. 2724-481
Your submission dated July 14, 2003

Dear Ms. Huebl:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable, subject to the comments listed below.

1. Under the "Precautionary Statements" section, please revise the statement " Wash thoroughly with soap and water after handling and before eating or smoking" to read " Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco."
2. Move the statement "Avoid hand- or sleeve-to-face exposure" to the "Directions for Use" section of your label.
3. Delete the statement "This product may not...from Wellmark International" from the Directions for Use section. The Agency will not allow statements on labels that we have not determined to be necessary restrictions. And, we will not allow restrictions on labels that we would not enforce. The Agency will also not allow restrictions on the label that may be interpreted to restrain trade (anti-trust laws). Finally, authorization to use data (which this is analogous to) is only required when the data are exclusive use studies.

A stamped copy of the label has been enclosed for your records. If you have any questions, please call Dr. William Sproat of my team at 703-308-8587.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Tau-fluvalinate (CAS #102851-06-9)..... 87.2%

OTHER INGREDIENTS: 12.8%

TOTAL 100.0%

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA
REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

NET CONTENTS

Lot No.

EPA Reg. No. 2724-481

EPA Est. No.

ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN 13 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

2724-481

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand- or sleeve-to-face exposure.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-248-7763 for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

Only for formulation into an insecticide for the following use(s): (1) other manufacturing use products, turf, indoor plants (including greenhouses) and outdoor ornamental plantings and landscapes, trees, shrubs, flower and foliage cuttings, containerized nursery stock, and on outside surfaces and around buildings; (2) uses for which US Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with US Environmental Protection Agency requirements.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding support of such uses.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture, or registration of any products without prior written authorization from Wellmark International.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food, or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of tau-fluvalinate technical may be disposed of on site or at any approved waste disposal facility.

CONTAINER DISPOSAL (Metal): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

WARRANTY AND CONDITIONS OF SALE

Seller warrants that the chemical composition of this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. Seller makes no other warranty, express or implied, concerning the use of this product other than as indicated on the label.

Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given on the label.

For information or in case of an emergency, call 1-800-248-7763

Wellmark International
Schaumburg, IL 60173
Made in USA

Explore Registrations					
Reg Number:	2724-481	Reg. Type:	Product Registration - Section 3	Status:	Conditionally Registered (02-Jan-1
Name:	TAU-FLUALINATE TECHNICAL			<View Registration Details>	
(No New Receipts)					
S:	Submission Type	OPP Rec'd Date	Resubmission	Description	
<div style="display: flex;"> <div style="flex: 1;"> <p>...Decisions...</p> <ul style="list-style-type: none"> D: 330203; 2724-481;300;LABEL REVISION;I S: 742813 7/16/03, Amendment, 2724 D: 192336; 2724-481;350;GENERAL CORRE D: 192335; 2724-481;345;FORMULA CHANG D: 192334; 2724-481;300;LABEL REVISION;I D: 192333; 2724-481;345;FORMULA CHANG D: 192332; 2724-481;405;ADVERSE DATA (6 D: 192331; 2724-481;300;LABEL REVISION;I D: 192330; 2724-481;300;LABEL REVISION;I D: 192329; 2724-481;300;LABEL REVISION;I D: 192328; 2724-481;300;LABEL REVISION;I D: 192327; 2724-481;300;LABEL REVISION;I D: 192326; 2724-481;300;LABEL REVISION;I D: 192325; 2724-481;300;LABEL REVISION;I D: 192324; 2724-481;300;LABEL REVISION;I D: 192323; 2724-481;300;LABEL REVISION;I D: 192322; 2724-481;300;LABEL REVISION;I D: 192321; 2724-481;300;LABEL REVISION;I D: 192320; 2724-481;300;LABEL REVISION;I D: 192319; 2724-481;300;LABEL REVISION;I </div> <div style="flex: 2;"> <p>S: 742813 Reg #: 2724-481</p> <p>Submission Type: Amendment</p> <p>Resubmission?: <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Decision #: 330203; 300;LABEL REVISION;NO DATA REQUIRED;</p> <p>Submitter Company: WELLMARK INTERNATIONAL</p> <p>Application Date: 14-Jul-2003</p> <p>OPP Received Date: 16-Jul-2003 Date Sent to Risk manager: 18-Jul-2003</p> <p>Studies Included?: <input type="radio"/> Yes <input checked="" type="radio"/> No Fast Track?: <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Form A Signed? <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </p> <p>Form B Signed? <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </p> <p>Reviewer: Sproat, William</p> <p>Received DT: 18-Jul-2003 Editable Due DT: </p> <p>Admin Due DT: 14-Oct-2003 Response: 0, 30-Jul-2003</p> <p>Priority Weight: Priority Points: </p> <p>Comments: 2001-1</p> </div> </div>					

Bill - check 3rd paragraph under Directions for Use with Michele Knorr. I'm not quite sure they can require written authorization is a company

Receipt for Section 3

S: 742813

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: Amendment

Enter More Information

Company: 2724 WELLMARK INTERNATIONAL

V

Risk Manager: Registration Division, Risk Management Team 3

Product #: 2724-481

Product Name: TAU-FLUALINATE TECHNICAL

Override#:

Me Too:

Me Too:

Section 3:

Product Name:

Application Date: 14-Jul-2003

iP

OPP Rec'd Date: 16-Jul-2003

iP

Front End Date: 18-Jul-2003

iP

Risk Manager Send Date: 18-Jul-2003

iP

Fast Track: ☒ Studies: ☐ New Ingredient: ☐

Receipt Description:

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



July 14, 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs 7504C
U.S. Environmental Protection Agency
Room 266A Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

ATTENTION: Dr. William Sproat, Team 13

SUBJECT: REVISED LABEL AMENDMENT PER PRN 2001-1 (FIRST AID)
FOR TAU-FLUVALINATE TECHNICAL/EPA REG. NO. 2724-481

Dear Dr. Sproat:

Enclosed is a completed EPA Form 8570-1 and 5 copies of revised labeling for the above product per PRN 2001-1 (First Aid). I have also included one highlighted label to indicate where changes were made. The First Aid was revised based on suggested text from the PR Notice.

If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL

Nancy Huebl

Nancy Huebl
Regulatory Specialist

enclosure

cc: G. Sandberg/C. Elmi/J. Richardson



REGULATORY LABEL DATA SHEET

File Name: Amend first aid 403

Data Sheet Date: April 2003

Product: TAU-FLUVALINATE
TECHNICAL

EPA Reg #: 2724-481

Approved: Amendment submitted 4/03

Supercedes: 10/97

OVERVIEW: Label amendment to revise First Aid (with exact text) per PRN 2001-1

Page #	Description of Major Changes
1	Moved "Precautionary Statements – Hazards to Humans... - Warning" to precede First Aid Removed Specific Gravity – not required
2	Revised First Aid with exact text per PRN 2001-1
3	Directions for Use: added trees, containerized nursery stock, perimeter treatment Corrected phone number Address change

TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Tau-fluvalinate (CAS #102851-06-9)..... 87.2%

OTHER INGREDIENTS: 12.8%

TOTAL 100.0%

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA

REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

~~May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand or sleeve to face exposure.~~

NET CONTENTS

Lot No.

~~Specific gravity: 1.29~~

EPA Reg. No. 2724-481

EPA Est. No.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand- or sleeve-to-face exposure.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-248-7763 for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

FIRST AID

~~IF SWALLOWED:~~ Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

~~IF IN EYES:~~ Flush eyes with plenty of water. Get medical attention if irritation persists.

~~IF ON SKIN:~~ Wash with plenty of soap and water. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

Only for formulation into an insecticide for the following use(s): (1) other manufacturing use products, turf, indoor **plants** (including greenhouses) and outdoor ornamental plantings and plantscapes, **trees**, shrubs, flower and foliage cuttings, **containerized nursery stock, and on outside surfaces and around buildings**; (2) uses for which US Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with US Environmental Protection Agency requirements.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding support of such uses.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture, or registration of any products without prior written authorization from Wellmark International.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food, or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of tau-fluvalinate technical may be disposed of on site or at any approved waste disposal facility.

CONTAINER DISPOSAL (Metal): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

WARRANTY AND CONDITIONS OF SALE

Seller warrants that the chemical composition of this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. Seller makes no other warranty, express or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given on the label.

For information or in case of an emergency, call 1-800-~~347~~**248**-7763

Wellmark International
~~Bensenville~~**Schaumburg**, IL 601**7306**
Made in USA

18: George LaRocca/RD **SPRAY DRIFT TASK FORCE**

April 25, 2002

Donald R. Flint, Ph.D.
Chmn., Administrative Comm.
Bayer Corporation
12711 Sagamore
Leawood, KS 66209
TEL: (913) 491-6717
FAX: (913) 469-8938

Via Certified Mail
Mr. Steve Spaulding
Wellmark International
1100 East Woodfield Road, Suite 500
Schaumburg, IL 60173

Re: Wellmark Rights in SDTF Data

David Valcore
Chmn., Technical Comm.
Dow AgroSciences
9330 Zionsville Road
Building 304
Indianapolis, IN 46268
TEL: (317) 337-7933
FAX: (317) 337-7922

Dick Palmquist
Treasurer
FMC Corporation
800 Apple Hill Drive
West Chester, PA 19380
TEL: (610) 431-7982
FAX: (610) 431-6202

Andrew J. Hewitt, Ph.D.
David R. Johnson, Ph.D.
Project Managers
Stewart Agricultural Research
Services, Inc.
P.O. Box 509
Macon, MO 63552
TEL: (660) 762-4240
FAX: (660) 762-4295

Charles A. O'Connor, III
Secretary/Counsel
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006
TEL: (202) 496-7586
FAX: (202) 496-7756

Denis Hayley
Controller
Hayley Associates
2900 Shipmaster Way, #220
Annapolis, MD 21401
TEL: (410) 571-6624
Fax: (410) 571-6355

Dear Mr. Spaulding:

In response to a request from the Environmental Protection Agency (EPA), the Spray Drift Task Force (SDTF) recently identified fluvalinate among the active ingredients requiring spray drift data for which SDTF nonmembers hold registrations. Because Wellmark International (Wellmark) acquired its fluvalinate registrations (EPA Reg. Nos. 2724-478, -481) from an SDTF member, we take this opportunity to outline Wellmark's limited rights under the SDTF Joint Data Development Agreement (JDDA) to rely on SDTF data to support those transferred registrations. Because Wellmark may later need to obtain additional rights in SDTF data, we also summarize the terms of SDTF membership and the opportunity to negotiate a data license in lieu of joining the SDTF.

Although we have not reviewed Wellmark's transfer agreement with Sandoz, we note that Sandoz's rights in SDTF data as a member of the SDTF are only those provided in the JDDA. Under Paragraph 15.5 of the JDDA, an SDTF member that transfers a product line to a nonmember may provide its transferee the limited right to rely on SDTF data to support the transferred registrations, but not to support "any further amendments or other changes" to the transferred registrations or any other registrations. Thus, as a transferee Wellmark cannot rely on SDTF data to amend the transferred registrations with respect to spray drift labeling, registered crops and use patterns, and the sources of active ingredients identified on a confidential statement of formula, without making an offer to compensate the SDTF.

Although the JDDA gives transferees no right to rely on SDTF data to support any amendments to the transferred registrations, the SDTF has decided to forego data compensation in the limited circumstance where a transferee amends those registrations simply to adopt EPA-required, standard label language pursuant to a Reregistration Eligibility Decision,

SPRAY DRIFT TASK FORCE

Mr. Steve Spaulding
April 25, 2002
Page 2

Pesticide Registration (PR) Notice, or other similar EPA guidance. This policy does not apply to non-standard amendments (such as alternate language proposed by a registrant) or amendments that require specific data (such as filling in the blank in an EPA-required statement like "do not apply this product within ____ meters of wetland areas"). Further, the SDTF's decision to forego compensation does not relieve Wellmark from its obligation to submit or cite (and offer to pay for) the spray drift data required to support *any* amendments to the transferred registrations. Accordingly, the SDTF will expect Wellmark to make an offer to pay in connection with any such amendment, notwithstanding the SDTF's stated willingness to forego data compensation for these routine amendments.

In the event that Wellmark later needs rights in spray drift data to support an amendment to the transferred registrations or any other registration, the SDTF believes that Wellmark's most cost-effective way to discharge its spray drift data obligations is to join the SDTF. SDTF membership gives Wellmark joint ownership of the SDTF's substantial generic spray drift database – developed at a cost of more than \$22 million. Wellmark can use this database in the United States and abroad in support of its current and future registrations and in support of end-use products made from Wellmark's manufacturing-use products and registered by its customers.

Currently, the cost of membership under the SDTF JDDA is \$888,959.16, which includes the total membership assessments since 1990 (\$469,500.00), the interest thereon (\$366,196.16), and a testing risk assessment (\$53,263.00). To ease the up-front financial burden of membership, the SDTF allows new members to pay the cost of membership in three equal installments (\$296,319.72) over the first two years of membership, with applicable interest accruing on the unpaid balances. While the cost is substantial, this collaborative, industry-wide effort provides each member with access to data that are both superior to, and less costly and more broadly applicable than, any data that any individual company could hope to develop on its own products for the current cost of SDTF membership.


As an alternative to a registrant's joining the SDTF, the SDTF members recently authorized the licensing of SDTF data under appropriate circumstances. Assuming that its future needs for spray drift data are limited, Wellmark may qualify to license the right to rely upon SDTF data without joining the SDTF. Under the new licensing authority, the SDTF Officers will negotiate licenses based on the licensee's avoided testing costs. Hence, the license fee in some cases would reduce the amount of data compensation substantially below the cost of membership, and, furthermore, the license fee will apply to the cost of SDTF membership, if Wellmark later decides to join the SDTF.

SPRAY DRIFT TASK FORCE

Mr. Steve Spaulding
April 25, 2002
Page 3

Please do not hesitate to contact me with any questions about the SDTF.

Sincerely yours,



Charles A. O'Connor, III
Secretary and Counsel

CAO/ph

cc: Jay S. Ellenberger, Associate Director, EPA Field & External Affairs Division
George T. LaRocca, Product Manager, Team 13, EPA Registration Division



November 30, 2001

Ms. Kylie Rothwell (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway Room 266A
Arlington VA 22202

Subject: EPA Gold Seal Request

Dear Ms. Rothwell:

Our overseas affiliates are requesting verification of U.S. registration for a Wellmark International product. At this time, Wellmark International respectfully requests a proof of registration letter bearing the EPA Gold Seal for the product listed below:

<u>Product</u>	<u>EPA Reg. No.</u>
Tau-Fluvalinate Technical	2724-481

Because of the continual requests for the same product, would you please provide us with four copies of this certificate. Please return the documents in the enclosed self-addressed stamped envelope.

Thank you for your assistance. If you should have any questions, please feel free to contact me directly at 847.330.5378 or jackie.richardson@wellmarkint.com.

Thank you,

A handwritten signature in black ink that reads "Jackie Richardson".

Jackie Richardson
Registration Specialist
Wellmark International

enclosure





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 12 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

I, **George T. LaRocca**, Product Manager 13, Insecticide Branch, Registration Division, Office of Pesticide Programs, Office of Prevention, Pesticide and Toxic Substances, United States Environmental Protection Agency (EPA), confirm that the pesticide product(s) listed below is, as of the date of this letter, registered with EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and that accordingly, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. I am attaching to this letter a copy of the label(s) for the pesticide product(s) which is a true and correct copy of the label(s) on file with EPA.

Registration of this/these product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the purchase, sale, application, use, storage, or disposal of the product(s). Further, the recipient of this letter is on notice that the status of the referenced registration may change subsequent to the date of this letter. EPA assumes no responsibility to notify any recipient of this letter of any change in the status of the registration(s) listed below, and advises the recipient of this letter to request that the registrants provide this information if the status of the registration(s) should change.

EPA has issued registration numbers for the product(s) listed below to:

WELLMARK INTERNATIONAL
1100 East Woodfield Road, Suite 500
Schaumburg, Illinois 60173

EPA Registration Number(s)
2724-481

Product Name(s)
Tau-Fluvalinate Technical

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐
☐
☒

Registration
Amendment
Other

OPP Identifier Number

259828

Application for Pesticide - Section I

1. Company/Product Number Wellmark International 2724-481	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tau-fluvalinate Technical	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Wellmark International 1000 Tower Lane Suite 245 Bensenville, IL 60160-1042 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

NOTIFICATION

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated FEB 16 1998
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Registrant name and address updates; minor label revisions per PR Notices 97-4, 97-5, & 97-6. This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 245 kg. / 540 lbs.		5. Location of Label Directions <input checked="" type="checkbox"/> ON LABEL	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Eileen T. Valenta		Title Federal Regulatory Project Manager	
		Telephone No. (Include Area Code) 630-227-6019	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Federal Regulatory Project Manager	
4. Typed Name Eileen T. Valenta		5. Date February 10, 1998	

112

FEB 16 1998

October 97 ATAf1TEA.97A

REGULATORY LABEL DATA SHEET

File Name:	ATAf1teA.97a	Data Sheet Date:	October 1997
Product:	TAU-FLUVALINATE TECHNICAL	EPA Reg #:	2724-481 (55947-104)
Approved:	Notification 10/97	Supersedes:	6/12/96 Notification

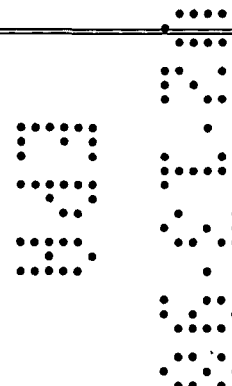
OVERVIEW: Notification submitted to change name/address from Sandoz to Wellmark, update per PRN 97-6, 97-5, 97-4

Page #	Description of Major Changes
1	<p>Ingredient Statement:</p> <p>Removed tau-fluvalinate chemical name, added CAS # (PRN 97-5)</p> <p>Per PRN 97-6, "Inert" changed to "Other"</p> <p>Removed patent reference</p> <p>EPA Reg. No. changed from 55947-104 (ag) to 2724-481 (Transfer to Wellmark)</p> <p>Added Made in USA (NAFTA)</p> <p>Name/address change Sandoz to Wellmark</p>
2	<p>Statement of Practical Treatment changed to First aid (CLI), updated per 12/96 Label Review Manual</p> <p>Environmental Hazards Statement updated per 12/96 Label Review Manual</p> <p>DFU - last paragraph - reference to Sandoz changed to Wellmark</p>
3	<p>S&D - Added specific descriptors to section for clarity</p> <p>Sandoz ag warranty changed to Wellmark warranty</p> <p>Information telephone number added (PRN 97-4)</p>

REGULATORY: Eileen Valenta

MARKETING:

EPA PRODUCT MANAGER: G. LaRocca PM13



TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Tau-fluvalinate (CAS #102851-06-9) 87.2%

OTHER INGREDIENTS: 12.8%

TOTAL 100.0%

EPA Reg. No. 2724-481

EPA Est. No.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

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May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand- or sleeve-to-face exposure.

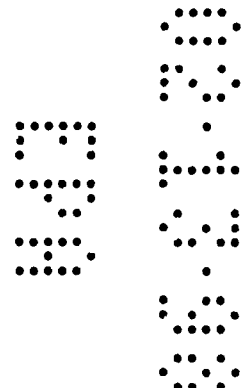
Wellmark International
Bensenville, IL 60106

Made in USA

NET CONTENTS

Lot No.

Specific gravity: 1.29



FIRST AID

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PHYSICAL AND CHEMICAL HAZARDS

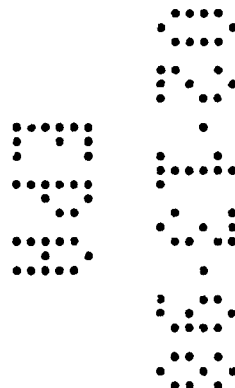
Do not use or store near heat or open flame.

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STORAGE AND DISPOSAL

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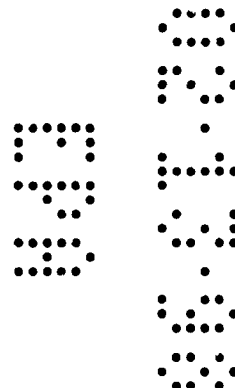
PESTICIDE DISPOSAL: Wastes resulting from the use of tau-fluvalinate technical may be disposed of on site or at any approved waste disposal facility.

CONTAINER DISPOSAL (Metal): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

WARRANTY AND CONDITIONS OF SALE

Seller warrants that the chemical composition of this product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use. Seller makes no other warranty, express or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given on the label.

For information or in case of an emergency, call [phone number]





NOTIFICATION
FEB 16 1998

Mr. George T. LaRocca
Product Manager #13
EPA - OPP-RD-IRB
Room 204, Crystal Mall, Building 2
1921 Jefferson Davis Highway
Arlington, VA 22202

February 10, 1998

SUBJECT: Label and CSF Updates
Taufluvalinate Technical
EPA Registration Number 2724-481

Dear Mr. LaRocca:

As agent for, and on behalf of Wellmark International and in compliance with PR Notices 97-4, 97-5 and 97-6, I respectfully submit a notification to the registration of the subject product. Also reflected in this document are updates to the registrant name and address.

A copy of the revised label (highlighted with strikeout text and accompanied by a summary page) and two original signed Confidential Statements of Formula have been included in this application. Should any further details or explanations be required, please do not hesitate to contact me.

Sincerely yours,

A handwritten signature in cursive script, reading "Eileen T. Valenta".

Eileen T. Valenta
Federal Regulatory Project Manager

Phone
(630) 227-6019

FAX
(630) 227-6065

e-mail
Eileen.Valenta@Wellmarkint.com



JUL 10 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

NOVARTIS CROP PROTECTION, INC.
P.O. BOX 18300
GREENSBORO, NC 274198300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/07/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal has not been analyzed for compliance with PR Notice 86-5, due to the fact that it was submitted under the requirements of FIFRA Section 6(a)2. A copy of your transmittal letter is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted.

221	5548682
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REF: 1E04020

This study was
reviewed under
the fluvastatin
RED.

G. Labrecque
12/14/2002



Lee Hubbard, Ph.D.
Regulatory Affairs
Tel 336-632-7034
Fax 336-292-6374
Internet Lee.Hubbard@cp.novartis.com

Certified Mail

Novartis Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
www.cp.us.novartis.com

Tel 336 632 6000

445966-00

July 2, 1998

Office of Pesticide Programs [6(a)(2)]
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Attention: Mr. George T. LaRocca, Product Manager, Team 13

SUBJECT: Report of Potential Adverse Effects – tau-fluvalinate
(PC Code: 109302)

Dear Mr. George T. LaRocca:

With this letter Novartis is providing information on tau-fluvalinate in accordance with the Agency's current interpretation of FIFRA § 6 (a)(2) reporting requirements. Novartis does not hold a U. S. registration for fluvalinate or enantiomerically resolved tau-fluvalinate. Wellmark International is the registrant for tau-fluvalinate in the U.S. Novartis has a pending action (submitted by Sandoz Agro, Inc.) to establish tolerances for tau-fluvalinate in or on apples, kiwi, and oriental pears (PP 1E4020). Novartis recently discovered a 1986 reproductive toxicology report in our files. We have not been able to determine if a 6(a)(2) report was filed with the Agency regarding the findings of this study. A summary of the observations provided by Dr. Amechi Chukwudebe, Toxicologist, Novartis Crop Protection, Inc. is included below:

The test substance, half-resolved fluvalinate technical, was examined for effects on the growth and reproductive functions of two consecutive generations in the rat in a study entitled "Effect of Half-Resolved Fluvalinate Technical on Reproductive Function of Two Generations in the Rat". Dietary test substance concentrations administered were 0, 10, 25 and 125 ppm. This fluvalinate study, completed in July 1986, was sponsored by Mitsubishi Chemical Industries Ltd. and conducted at the facilities of Huntingdon Research Centre Ltd. in England. The following adverse findings were observed in this study:

- At the 125 ppm dietary exposure level, most pups in 15/28 litters of F0 females and 6/20 litters of F1 females showed tremors during the lactation period - generally around day 14. Tremors were not observed at any of the other dietary exposure levels tested.
- At 125 ppm, 6 animals (3 F0 males, 1 F0 female and 2 F1 males) showed areas of cutaneous ulceration. In the males, these ulcerations regressed and were not present at terminal autopsy. In the F0 female the ulceration was present at the time of parturition and covered a large area;

both the female and the resulting litter appeared to be affected. This F0 animal and the litter were, therefore, killed on day 5 postpartum.

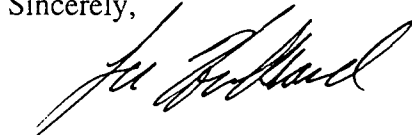
Among adult animals, the incidence of scabbing and fur loss at 25 and 125 ppm were marginally greater than for control animals. The incidence of scabbing and fur loss at 10 ppm was unaffected by treatment.

In this two-generation reproduction study, all growth and reproductive parameters evaluated at 10 ppm were essentially similar to that of control animals.

Please find enclosed three copies of the toxicology report "Effect of Half-Resolved Fluvalinate Technical on Reproductive Function of Two-Generations in the Rat"; EPA GDLN 83-4.

Please call me at 910-632-7034 if there any questions concerning this report.

Sincerely,



Lee Hubbard, Ph.D.
Senior Regulatory Manager

Enclosures

cc: Susan Lewis, Branch Chief, Insecticides (letter only)
Steve Spalding, Manager, Regulatory Affairs, Wellmark, International (letter only)

**VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)**

1. Name and Address of Submitter

Novartis Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Potential adverse effect [6(a)(2)] related to pesticide petition number 1E4020 to establish tolerances for tau-fluvalinate in or on apples, kiwi, and oriental pears

3. Transmittal Date

July 2, 1998

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 of 2	TRANSMITTAL DOCUMENT	N/A
44596601	2 of 2	EFFECT OF HALF-RESOLVED FLUVALINATE TECHNICAL ON REPRODUCTIVE FUNCTION OF TWO GENERATION RATS (/2-84; HRC Report No. MCI 56/8694)	83-4

Company Official: Hubbard, H. Lee
(Name)

(Signature)

Company Name: NOVARTIS CROP PROTECTION, INC.

Company Contact: Hubbard, H. Lee
(Name)

336-632-7034
(Phone)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 5, 1997

Mr. Steven R. Spaulding, Manager
Regulatory Affairs
Wellmark International
1000 Tower Lane, Suite 245
Bensenville, IL 60106

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Mr. Spaulding:

Pursuant to your request in your letter and transfer agreement of June 10, 1997, we have approved the transfer of the following registrations and data from **Sandoz Agro, Inc.**, company number 55947, to **Wellmark International**, company number 2724.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
Enstar II Insect Growth Regulator (Enstar 5E)	55947-82	2724-476
Altosid 5E-FZ-515 (Diacon)	55947-94	2724-477
Mavrik Aquaflow Insecticide	55947-101	2724-478
Fluvalinate 25% Bulk An Insecticide For Manufacturing Use Only	55947-102	2724-479
Fluvalinate 80% Concentrate	55947-103	2724-480
Fluvalinatte Technical	55947-104	2724-481
Fluvalinate 22.3%F Bulk	55947-106	2724-482
Sandoz 9404 Spray	55947-158	2724-483

<u>24(c) Products Reg. No.</u>	<u>Old Parent Reg. No.</u>	<u>New Parent Reg. No.</u>
CA-96-0010	55947-101	2724-478
PA-93-0003	55947-101	2724-478

PLEASE NOTE:

Your Transfer Agreement also requested transfer of "Sandoz Do-It-Yourself Garden Pest Control, 55947-92" which, according to our records, is in processing for cancellation due to registrant request during the 1997 Maintenance Fee process and therefore not transferrable.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

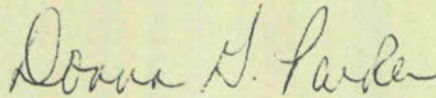
Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated June 10, 1997 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **Wellmark International** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460-0001

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,



Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: Robin Demouth
General Counsel & Secretary
Sandoz Agro, Inc.
1300 East Touhy Avenue
Des Plaines, Illinois 60018

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

345-5476140
17/25

JAN 3 1995

Mr. Michael Johnston
SANDOZ AGRO, INC.
1300 E. Touhy Avenue
Des Plaines, IL 60018

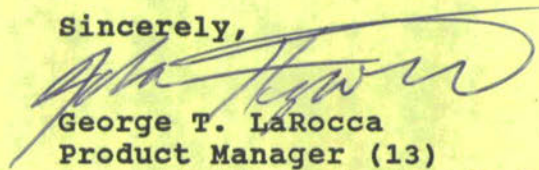
Dear Mr. Johnston:

Subject: Label Amendment-Change Chemical Name to
Official Recognized ISO & IUPAC
Common & Chemical Names
TAU-FLUVALINATE Technical
EPA Registration Number 55947-104
MAVRIK AQUAFLOW Insecticide/Miticide
EPA Registration Number 55947-101
Your Amended Applications Dated October 18, 1994

The amended labeling referred to above, reflecting the officially recognized ISO & IUPAC common and chemical name to refer to half resolved fluvalinate, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

Submit two (2) copies of the final printed labeling. A stamped copy is enclosed for your records.

Sincerely,


George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure:

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

TAU-FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

~~(α RS, 2R) fluvalinate [(RS α cyano 3 phenoxybenzyl~~
~~(R) 2 [2 chloro 4 (trifluoromethyl) anilino] 3 methyl~~
~~butanoate)]*.....87.2%~~
tau-fluvalinate [(RS)- α -cyano-3-phenoxybenzyl
N-(2-chloro- α,α,α -trifluoro-p-tolyl)-D-valinate]*.....87.2%

INERT INGREDIENTS:.....12.8%

TOTAL.....100.0%

*U.S. Pat. 4,260,633 & 4,411,912

EPA Reg. No. 55947-104
EPA Est. No. 55947-TX-1

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

OPEN CONTAINER IN WELL VENTILATED AREA.
DO NOT BREATHE FUMES

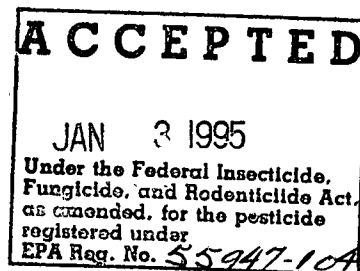
REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS LOT.

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand- or sleeve-to-face exposure.

SANDOZ AGRO, INC.
1300 East Touhy Avenue
Des Plaines, Illinois 60018

NET CONTENTS: 245 Kg (540 lbs.)
Lot No.: _____
Specific gravity: 1.29

IFLUTECA.94a



STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, estuaries, oceans or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

Only for formulation into an insecticide for the following use(s): other manufacturing use products, turf, indoor and outdoor ornamental plantings and landscapes. Uses for which U.S. Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and uses for experimental purposes that are in compliance with U.S. Environmental Protection Agency Requirements.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Sandoz Agro, Inc.

IFLUTECA.94a

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food or feed.

DISPOSAL: Wastes resulting from the use of Fluvalinate Technical may be disposed of on site or at any approved waste disposal facility.

Metal Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

LIMITATION OF WARRANTY AND LIMITATION OF LIABILITY

NOTICE: Read this Limitation of Warranty and Limitation of Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Sandoz or seller. All such risks shall be assumed by buyer or user.

Sandoz warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, under normal use conditions, subject to the risks described above. SANDOZ MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

In no event shall Sandoz or seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SANDOZ OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SANDOZ OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Sandoz and seller offer this product, and buyer and user accept it, subject to the foregoing limitations of warranty and limitation of liability, which may not be modified by any oral or written agreement.

Product Chemistry Review
RSB

HP
4/19/97

EPA Reg. No. or File Symbol 55947-104

Date Division Received 4-19-93

Products Manager No. 13 (LaRocca)

Product Name Fluvalinate Technical


Company Name Sandoz Crop Protection Corporation

100.0 Comments:

This application is registrant's justification of proposed certified limits for this product.

- a. Certified limits are based on five batch analysis of technical Fluvalinate and the variability in manufacturing process which is $\pm 5\%$ with respect to the nominal concentration.
- b. The proposed certified limits ($\pm 5\%$) are in compliance with 40 CFR part 158.175 (c)(3+4) and are acceptable.

Anna Skapars
4-28-93

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number 200513
		<input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	

Application for Pesticide:

Section I

1. Company/Product Number Sandoz Agro, Inc./55947-104	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sandoz Agro, Inc./Technical Fluvalinate	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Sandoz Agro, Inc. 1300 E. Touhy Ave. Des Plaines, IL 60018 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

ISO &

Amendment: To change chemical name to officially recognized IUPAC common & chemical names, thus reflecting half resolved nature of chemical.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted.		If "Yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other (_____)			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Michael R. Johnston	Title Registration Specialist	Telephone No. (Include Area Code) 708/390-3096
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Michael R. Johnston</i>	3. Title Registration Specialist	
4. Typed Name Michael R. Johnston	5. Date October 18, 1994	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your **Company Number**, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the **Product Number**.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Attachment 1

CORPORATE HEADQUARTERS

TEL 708.699.1616

January 11, 1994

Document Processing Desk (COADR)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M. Street (SW)
Washington, D.C. 20460

Attention: Change of Name and Address of Record

Dear Sir or Madam:

In the past year, Sandoz Agro, Inc. has completed the merger of the Zoecon Corporation into Sandoz Agro, Inc. and has moved primary product registration activities to the SAI headquarters in the Des Plaines, IL office. Therefore we are announcing a change in the name and address of record for Zoecon as follows:

EPA Company Number: 2724

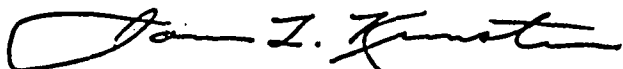
Old Name & Mailing Address: Zoecon Corporation
A Sandoz Company
12200 Denton Drive
Dallas, TX 75234

New Name & Mailing Address: Sandoz Animal Health
Sandoz Agro, Inc.
1300 East Touhy Ave.
Des Plaines, IL 60018

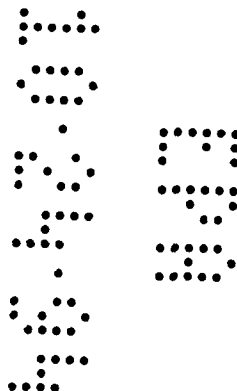
Effective Date: January 1, 1994

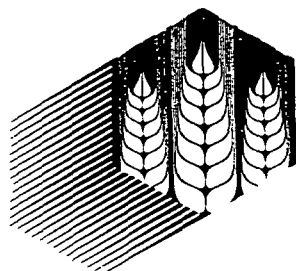
Contact Name & Phone: James Lee Kunstman
Phone: (708) 390-3664
FAX: (708) 390-3941

Sincerely,



James L. Kunstman, PhD.
Manager, Product Registration





THE AGROCHEMICALS HANDBOOK

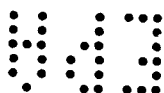
Third Edition

UPDATE 5 — JANUARY 1994



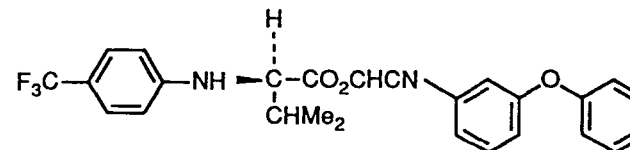
ROYAL
SOCIETY OF
CHEMISTRY
Information
Services

The Royal Society of Chemistry
Thomas Graham House
Science Park, Milton Road
Cambridge CB4 4WF England
Tel: Cambridge (0223) 420066



Insecticide/Acaricide

tau-fluvalinate



Common name: tau-fluvalinate (BSI, draft ISO-E)

Chemical names:

(*RS*)- α -cyano-3-phenoxybenzyl *N*-(2-chloro- α,α,α -trifluoro-*p*-tolyl)-*D*-valinate (IUPAC)
cyano(3-phenoxyphenyl)methyl *N*-[2-chloro-4-(trifluoromethyl)phenyl]-*D*-valinate (CA)

Trade names: Apistan (Sandoz); Klartan (Sandoz); Mavrik (Sandoz); Spur (Sandoz); Yardex (Zoecon).

Chemical family: trifluoromethyl; pyrethroid

Molecular formula: C₂₆H₂₂ClF₃N₂O₃

Molecular weight: 502.93

CAS Registry Number: 102851-06-9

Manufacturers: Sandoz.

Physical form: Viscous yellow oil (technical).

Boiling point: Greater than 450°C.

Vapour pressure: Less than 0.013 mPa at 25°C.

Specific gravity: 1.29 at 25°C.

Refractive index: n_D^{20} 1.541.

Stability: Technical material is stable for at least 1 year at temperatures up to 50°C. Undergoes decomposition on exposure to sunlight. Half-life on hydrolysis at 25°C and pH 3 or pH 6 is >30 days, but at pH 9 is <1 hour.

Corrosiveness: Non-corrosive to slightly corrosive, depending upon the metal.

Solubility: In water, 0.002 mg/l. Soluble in aromatic hydrocarbons, alcohols, diethyl ether, and dichloromethane. Partition coefficient (octanol/water) 7000.

Analysis of products: By HPLC with UV detection (W. L. Fitch et al. *Anal. Methods Pestic. Plant Growth Regul.* 1984, 13, 79), or by GLC. Details from Sandoz.

Analysis of residues: By GLC with ECD (W. L. Fitch et al. *Anal. Methods Pestic. Plant Growth Regul.* 1984, 13, 79; W. Specht et al. *Z. Anal. Chem.* 1980, 301, 300). Details from Sandoz.

Mode of action: Insecticide and acaricide with contact and stomach action.

Uses: Control of a wide range of insects (including Lepidoptera, aphids, thrips, leafhoppers, whitefly, etc.) and spider mites on indoor and outdoor ornamentals, trees, apples, pears, peaches, citrus fruit, vines, cereals, vegetables, cotton, tea, tobacco, and turf. Also used for control of *Varroa jacobsoni* in beehives.

Phytotoxicity: Non-phytotoxic when used as directed.

PESTICIDE DICTIONARY

Foamer

Action/Use

ACTION: Fungicide.

USE: For various Ascomycete, Basidiomycete, Deuteromycete fungi in cereals, fruit, vegetables.

FORMULATIONS: Dry granules, emulsifiable concentrate.

COMBINATIONS: Everest* (+ fenpropimorph + tridemorph), Twin* (+ fenpropimorph) (both BASF AG).

Registration Notes

OUTSIDE U.S.: Denmark: Twin.

Environmental Guidelines

SOLUBILITY: In water 900 mg/l (pH 1.1) - 45 mg/l (pH 78).

Safety Guidelines

SIGNAL WORD: CAUTION.

TOXICITY CLASS: III.

TOXICITY: (Rat): Oral LD₅₀ 1110 mg/kg (male); 674 mg/kg (female).(Rabbit): Dermal LD₅₀ >2000 mg/kg. Inhalation LC₅₀ >5 mg/l.

EMERGENCY TELEPHONE: 800-441-3637 (Du Pont).

Flusul* — see Basalin*.

Flutolanil — see Moncut*.

Flutriafol — see Ethirimol; Ferrax*; Imazalil; Impact*; Thiabendazole; Vincit*.

Fluvalinate — see tau-Fluvalinate.

tau-Fluvalinate

BP: Sandoz Agro, Inc. (Mavrik*, Mavrik Aquaflow*, Spur*)

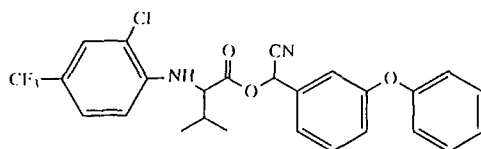
Sandoz Ltd. (Mavrik*, Klartan*)

Identification

COMMON NAMES: Tau-fluvalinate (ISO, ANSI, BSI); fluvalinate (ANSI).

CODE NUMBERS: CAS 102851-06-9; SHIA 109302.

Chemistry

COMPOSITION: (RS)- α -cyano-3-phenoxybenzyl N-(2-chloro- α , α -tri-fluoro-p-tolyl)-D-valinate (IUPAC).PROPERTIES: Viscous yellow oil. Boiling point >450°C. Vapor pressure <1 \times 10⁻⁷ Torr, at 25°C. Soluble in most organic solvents.

Fluvalinate

Action/Use

ACTION: Broad spectrum contact, stomach insecticide.

USE: For Coleoptera, Hemiptera, Lepidoptera, etc. on cereal, cotton,

fruit trees, plantation crops, potato, rape, vegetable, wine.

FORMULATIONS: Emulsifiable concentrate, flowable, ULV.

COMBINATIONS: Do not mix with strongly basic products.

Registration Notes

U.S.: Voluntary cancellation of dormant, non-bearing, and seed crop uses of Spur* on some fruits, nuts, vegetables, and tobacco. The manufacturer may sell or distribute existing stocks until April 1993.

Environmental Guidelines

HAZARDS: Fish: Toxic.

Safety Guidelines

SIGNAL WORD: WARNING.

TOXICITY CLASS: I.

TOXICITY: Tech (Rat): Oral LD₅₀ 261-282 mg/kg. Dermal >20,000 mg/kg. (Rabbit): Dermal LD₅₀ >20,000 mg/kg.

PROTECTIVE CLOTHING: Wear goggles, face shield, rubber gloves when opening or pouring formulated products.

Emergency Guidelines

FIRST AID: Get medical aid. Eyes, immediately flush with water.Skin: wash with plenty of soap, water. Ingestion, do NOT induce vomiting. Gastric lavage indicated.

Fluxofenim — see Concep* III.

Fly Bait Grits* Insecticide (bomyl) — Discontinued 1990 by HACO, Inc.

Fly-Bate* — see DDVP.

Fly-Die* — see DDVP.

Fly Fighter* — see DDVP.

FMC 5452 — see Endosulfan.

FMC 54800 — see Talstar*.

FMC 9044 — see Morocide*.

FMC 9102 (metiram) — Discontinued by FMC Corp.

FMC 9260 (tetramethrin) — Discontinued by FMC Corp.

FMC 10242 — see Carbofuran.

FMC 11092 — see Karbutilate.

FMC 17370 (resmethrin) — Discontinued by FMC Corp.

FMC 30830 — see Cypermethrin.

FMC 33297 — see Permethrin.

FMC 35001 — see Marshal*.

FMC 54800 — see Talstar*.

FMC 57020 — see Command*.

FMC 67825 — see Rugby*.

Foam

Foam as used in pesticide application is a milky, sloshy solution which releases the chemical to plant surfaces quickly. Foam applying equipment functions to produce many small bubbles by mixing the spray formulation with air and a foaming agent. The greatest advantage lies in the reduction of drift. Other benefits are an extension of application time (wind no longer being an important factor); better coverage, fewer reloading trips since less water is used, etc.

See Foaming Adjuvant.

Foam Buster*

BP: Helena Chemical Co.

Chemistry

COMPOSITION: Dimethylpolysiloxane.

Action/Use

ACTION: Silicone defoamer and antifoam agent.

USE: For aqueous solutions.

Registration Notes

U.S.: For food use limitations refer to Title 21, CFR, and 173-340.

Safety Guidelines

TOXICITY CLASS: IV.

TOXICITY: Nontoxic.

See Foam Suppressant.

Foam Fighter*

BP: Miller Chemical & Fertilizer Corp. (Foam Fighter*)

Identification

COMPOSITION: Dimethyl silicone fluid emulsion.

Action/Use

ACTION: Defoaming agent.

USE: Reduces foam in agricultural chemical sprayers, dip tanks.

Safety Guidelines

SIGNAL WORD: CAUTION.

TOXICITY CLASS: III.

(The) Foam Marker*

BP: HACO, Inc.

Chemistry

PROPERTIES: Clear, yellow liquid.

Action/Use

ACTION: Foam marking agent.

USE: Agricultural foam marking agent with softeners, conditioners.

Environmental Guidelines

SOLUBILITY: Complete in water.

Safety Guidelines

SIGNAL WORD: CAUTION (May cause eye irritation).

TOXICITY CLASS: III.

HANDLING AND STORAGE CAUTIONS: Harmful if swallowed. Do not use, pour, spill, or store near heat, open flame.

Emergency Guidelines

FLASHPOINT: Combustible.

FIRST AID: Ingestion, give 1-2 glasses of water. If conscious, induce vomiting by touching back of throat with finger or blunt object. Get medical aid.

See Foam Marking Agent.

Foam Marking Agent

For use in foam generating equipment to mark limits of spray swath and thereby avoid overlap or missed areas. Highly visible, stable foam. Example: AgRHO FM* (Rhône-Poulenc Surfactants & Specialties).

Foam Suppressant

Spray adjuvant useful for suppressing both surface foam and entrained air.

Some examples are: Surfynol* (Air Products & Chemicals, Inc.); Foamgard* (Custom Chemicides); Foam Buster* (Helena Chemical Co.); Anti-Foam* (Kalo, Inc.); Foamex* (Rhône-Poulenc Surfactants & Specialties); Bubblegon* (Sagap); Taylor* Antifoams (Taylor Chemical); No Foam (Wilbur-Ellis Co.).

Foamaster*

BP: Henkel Corp.

Action/Use

ACTION: Defoaming-antifoam.

Foamer*

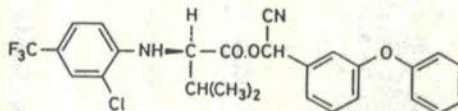
BP: Helena Chemical Co.

Chemicals are cross-referenced by common and trade name
 * — Trade Name/R/TM BP — Basic Producer F — Formulator
 Information not updated by company for 1994

6690 Tau-fluvalinate

 $C_{26}H_{22}ClF_3N_2O_3$ (502.9)

pyrethroid insecticide



Nomenclature

Common name tau-fluvalinate (BSI, draft E-ISO). **Chemical name (IUPAC)** (RS)- α -cyano-3-phenoxymethyl N-(2-chloro- α,α,α -trifluoro-p-tolyl)-D-valinate. (C.A.) cyano(3-phenoxymethyl)-N-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate (9CI). CAS RN /102851-06-9/ tau-fluvalinate; /69409-94-5/ fluvalinate (DL-isomers) - many references in the literature have been made, erroneously, to the latter rather than the former.

Development

Insecticidal activity of the various stereoisomers reported by C. A. Henrick *et al.* (*Pestic. Sci.*, 1980, **11**, 224) and by R. J. Anderson (*J. Agric. Food Chem.*, 1985, **33**, 508). Tau-fluvalinate, has replaced fluvalinate, both introduced by Zoecon Corp. (now owned by Sandoz Agro AG) (USP 4 260 633; 4 411 912): **Trade Mark** 'Mavrik', 'Klartan', 'Apistan' (veterinary) (Zoecon).

Properties

TC tau-fluvalinate is a viscous yellow oil; **b.p.** >450 °C (extrapolated); **v.p.** <0.013 mPa (25 °C); ρ 1.29 g/cm³; n_D^{20} 1.541. **Solubility**: 0.002 mg/kg water; freely soluble in alcohols, aromatic hydrocarbons, dichloromethane, diethyl ether. **K_{ow}** 7000. **Stable** > 1 y on storage at 50 °C; exposure to sunlight DT₅₀ 9.3-10.7 min (aqueous solution buffered pH5), c. 1 d (thin film on glass), 13 d (on soil surface); on hydrolysis (25 °C) DT₅₀ >30 d (pH3 and pH6), <1 h (pH9) ester moiety and ultimately the trifluoromethyl group hydrolysed at high pH; Soil DT₅₀ 6-8 d (various soil types with o.m. 0.2-1.8%)

Formulations

'Apistan', VP (10 g/kg plastic strip); 'Mavrik 2E', EC (240 g/l), 'Klartan', 'Mavrik 2F', SC (240 g/l). **Mixtures**: 'Amalux', (40 g tau-fluvalinate + 300 g quinalphos/l); 'Mavrik B', EC (72 g tau-fluvalinate + 200 g thiometon/l); 'Procarb' (Nippon Soda), WP (50 g tau-fluvalinate + 30 g hexythiazox/kg); 'Torero', twin pack (tau-fluvalinate + clofentezine). **Discontinued formulations**: 'Mavrik HR', EC; 'Spur', EW.

Uses

Tau-fluvalinate is potent, broad-range, foliar-applied insecticide and acaricide effective at 56-168 g AI/ha against Aphididae, Cicadellidae, Lepidoptera, Thysanoptera, Tetranychidae and *Trialeurodes vaporariorum* on cotton, fruit trees, ornamentals, vegetables, trees and vines. Also used to control *Varroa jacobsoni* in beehives.

Toxicology

Mammalian toxicity. Acute oral LD₅₀: for rats >3000 mg tau-fluvalinate/kg. Acute percutaneous LD₅₀: for rats >20 000 g fluvalinate/kg; for rabbits >2000 mg/kg; a mild skin and mild to moderate eye irritant. Acute inhalation LC₅₀ (4-h) >5.1 mg tau-fluvalinate (as 240 g/l EC)/l air. In feeding trials NOEL for rats 1 mg/kg daily.

Non-mammalian toxicity. Acute oral LD₅₀ for bobwhite quail >2510 mg tau-fluvalinate/kg. LC₅₀ (8-d) for mallard duck and bobwhite quail >5620 mg/kg diet; no effect observed on their reproduction up to 900 mg/kg diet (highest dose tested). **Fish toxicity** LC₅₀ (96-h): for carp 0.0048 mg/l; for rainbow trout 0.0029 mg/l, LC₅₀ (48-h) for *Daphnia* 0.0074 mg/l. Owing to

Continued on next page

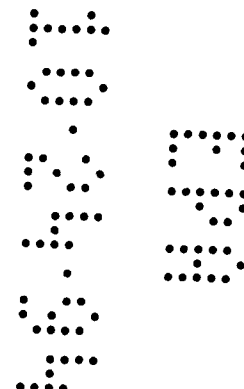
6690 Tau-fluvalinate *continued*

the low dosages needed for insect control, field use is unlikely to generate problems but it should not be applied where spray drift to aquatic systems can occur.

Analysis

Product analysis by hplc (W. L. Fitch *et al.*, *Anal. Methods Pestic. Plant Growth Regul.*, 1984, 13, 79) or by glc with FID. **Residues** determined by glc with ECD (*idem, ibid.*).

USE THE INDEXES TO FIND THE ENTRY NUMBER



Page 10 of 13 Amendment for Name Changes of CAS RN 102851-06-9

BS 6916: Part 11: 1989

Specification for general design, performance, safety and construction requirements for internal combustion engines

Defines minimum requirements for the general design, performance, safety and construction of portable, hand-held, internal combustion engines. Includes the technical data to be available to the user, the minimum requirements for the operator's manual and user instructions and tools. No current standard is superseded.

8 PAGE GR 5

AGE/29

BS 6979: 1989

Method for measurement of static deflection of power presses

Applies to static conditions. Mainly applicable to mechanical open-front type with capacities up to and including 2500 kN, it may also be applied to straight-sided and hydraulic presses. Additionally, it may be applied to presses with capacities over 2500 kN. No current standard is superseded.

20 PAGE GR 5

MTE/1

BS 6989: 1989

Guide to safety of storage equipment for loose bulk material

Covers the special safety rules for construction (design and manufacture), installation (design, manufacture and entry into service) and utilization (operation and maintenance) stages of hoppers, silos, storage bins and bunkers and bin gates. No current standard is superseded.

4 PAGE GR 3

MHE/9

BS 6999: 1989

Specification for vitreous-enamelled low-carbon-steel

fluepipes, other components and accessories for solid-fuel-burning appliances with a maximum rated output of 45 kW

Specifies the requirements and appropriate tests for internal, freely exposed fluepipes. No current standard is superseded.

12 PAGE GR 5

AGE/2

BS 7013: 1989

Specification for dental gypsum products

Classifies and specifies requirements and test methods for gypsum products for dental purposes, e.g. oral impressions, models, casts or dies. Supersedes BS 4598: 1970, BS 4721: 1971 and BS 4796: 1972

8 PAGE GR 5

HCC 34

BS 7026: 1989

Method for detection of hydrogen sulphide in liquefied petroleum gases using lead acetate

The presence of hydrogen sulphide at concentrations of greater than 4 mg per m³ of liquefied petroleum gas is detected by passing a vaporized sample over moist lead acetate paper under controlled conditions. No current standard is superseded.

4 PAGE GR 5

PTC 13

BS 7061: 1989

Specification for volume and file structure of compact read-only optical disks (CD-ROM) for information interchange

Specifies the volume and file structure of compact read-only optical disks (CD-ROM) for the interchange of information between users of information processing systems. No current standard is superseded.

4 PAGE GR 8

IST/11

BS 7071: 1989

Specification for portable residual current devices

Requirements for rating, design, construction and testing for portable residual current devices having a rated voltage not exceeding 250 V single-phase a.c., rated current not exceeding 16 A, a rated frequency not exceeding 400 Hz and a rated residual operating current not exceeding 30 mA. No current standard is superseded.

32 PAGE GR 8

PEL/11

BS 7089: 1989

Definition for nonwovens. Establishes a definition for nonwovens. No current standard is superseded.

4 PAGE GR 1

TCM/19

BS 7150: 1989

Code of practice for intruder alarm systems with mains wiring communication

Recommendations for construction, installation and operation of intruder alarm systems using an existing mains electrical circuit to provide interconnection between components. No current standard is superseded.

4 PAGE GR 3

FHM/45

Automobile series

BS AU 1c: 1989

Specification for dimensions of '50' fifth wheel king pin for semi-trailers

Gives basic, mounting and interchangeability dimensions. Supersedes BS AU 1b: 1977

4 PAGE GR 2

AUE/13

BS AU 16c: 1989

Specification for electrical cable connectors (17.5 A maximum continuous rating). Specifies requirements for bullet and tube type connectors. Supersedes BS AU 16: 1963 and BS AU 39: 1964 which was withdrawn in 1983.

4 PAGE GR 3

AUE/16

BS AU 228:—

Impact tests on road vehicles

BS AU 228: Part 1: 1989

Specification for measurement techniques and general instrumentation. Specifies requirements and gives recommendations to facilitate comparisons between results obtained by different laboratories. No current standard is superseded.

4 PAGE GR 3

AUE/7

BS AU 228: Part 2: 1989

Specification for measurement techniques using optical instrumentation. Defines performance criteria

using an optical data channel to facilitate comparisons between results obtained by different laboratories. No current standard is superseded.

4 PAGE GR 2

RUM/40

Amendments

Please give the reference AMD... not the BS number

486: 1981

Specification for asbestos-cement pressure pipes and joints

AMENDMENT NO 1 GR 1 AMD 5532

499:—

Welding terms and symbols

499: Part 2: 1981 Specification for symbols for welding

AMENDMENT NO 1 GR 0 AMD 6118

535: 1987

Specification for light sources for miners' portable electric lamps

AMENDMENT NO 1 GR 2 AMD 5863

3656: 1981

Specification for asbestos-cement pipes, joints and fittings for sewerage and drainage

AMENDMENT NO 1 GR 0 AMD 5531

4398: 1989

Specification for compounding ingredients for rubber test mixes

AMENDMENT NO 3 GR 1 AMD 5217

4727:—

Glossary of electrotechnical, power, telecommunication, electronics, lighting and colour terms

4727: Part 2:—Terms particular to power engineering

4727: Part 2: Group 11: 1986

Generation, transmission and distribution of electricity terminology

AMENDMENT NO 1 GR 3 AMD 5524

5482:—

Code of practice for domestic butane and propane gas-burning installations

5482: Part 1: 1979 Installations in permanent dwellings

AMENDMENT NO 1 GR 2

5950:—

Structural use of steelwork in building

5950: Part 3: 1987 Code of practice for design of cold formed sections

AMENDMENT NO 1 GRATIS AMD 6957

Common names for pesticides

(Addendum to BS 1831)

The following names have been provisionally adopted by ISO and approved by Technical Committee C1C/48 'Common names for pesticides', for eventual inclusion in BS 1831. These names will not be included in a supplement to BS 1831: 1969 until final international adoption, when additional information will be given either in a supplement to the 1969 edition or in the next revision. The key in brackets following each name shows the classification of the pesticide by use, according to the key on page 6 of BS 1831: Part 1: 1985.

The layout of entries is as follows: Common names; pronunciation; (key); chemical name.

fluvalinate *fluo-uá-l-i-nát* (I/A)
(RS)- α -cyano-3-phenoxybenzyl N-(2-chloro- α,α,α -trifluoro-*p*-tolyl)-DL-valinate

tau-fluvalinate *tor-fluo-uá-l-i-nát* (I)
(RS)- α -cyano-3-phenoxybenzyl N-(2-chloro- α,α,α -trifluoro-*p*-tolyl)-D-valinate

A copy of this announcement may be obtained on application to Mr M R Bell, at BSI Head Office. The reference 89/50879 should be quoted, and a stamped addressed envelope enclosed.



Attachment 6

Our ref: ISO/TC 81

Secretariat of ISO/TC 81

Date: 1 February 1989

Dr A Riggenbach
Agro Development
Sandoz Ltd
4002 Basel
Switzerland

Dear Dr Riggenbach

ISO/TC 81 - Common names for pesticides and other agrochemicals
Proposed common names fluvalinate and tau-fluvalinate

Many thanks for your letter of 9 September 1988 and the trade mark reports and other information that was enclosed.

I can now tell you that the ISO/TC 81 Secretariat Committee has considered the responses to the circulation of the above two proposed common names, and I am pleased that, in each case, the name was considered acceptable. Accordingly both fluvalinate and tau-fluvalinate will be included in a list for letter ballot as a draft Addendum to ISO 1750.

These names can now be considered to have the status of draft ISO common names.

I am very grateful to you for facilitating the progress of these names which, as you know, has been less than straightforward.

Yours sincerely

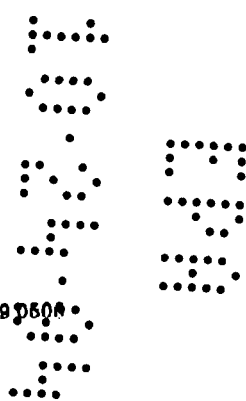
M R BELL
for UK Secretariat

MRB/JB

cc: Mr H Aebl, SNV



2 Park Street, London W1A 2BS Telephone: 01-629 9000 Telex: 266933 BSILON G Fax: (Gr2/3) 01-629 7500





Private Circulation

Document:

Attachment 7a

89/50880

Our ref:

CIC/48

Date:

13 February 1989

2 Park Street
London W1A 2BS
Telephone: 01-629 9000
Telex: 266933 BSILON G
Fax Gr 2/3: 01-629 0506

Technical Committee CIC/48
-Common names for pesticides

APPROVED COMMON NAMES

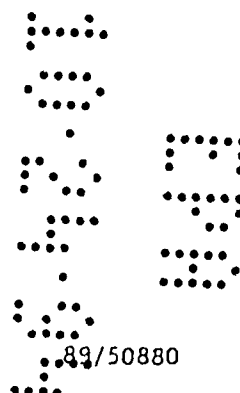
Key to serial numbers

fluvalinate (691)

tau-fluvalinate (827)

PE/1/CR

-1-



Attachment 7b

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 20 1993

300545521
38 54

I, George T. LaRocca, Product Manager 13, Insecticide-Rodenticide Branch, Registration Division, Office of Pesticide Programs, Office of Pesticides and Toxic Substances, U. S. Environmental Protection Agency, do hereby certify that the pesticide product listed below is currently registered with this Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, that the label attached is a true, correct, and compared copy of the correspondence of record, and that the product may be sold and marketed in the United States of America for the uses indicated on the label.

The product registration listed below has been issued to:

SANDOZ AGRO, INC.
1300 East Touhy Avenue
Des Plaines, IL 60018

EPA Registration Number

55947-104

Name of Product

FLUVALINATE TECHNICAL

IN WITNESS WHEREOF

I have hereunto set my hand
and affixed the seal of the
U.S. Environmental Protection
Agency this 20th day of
December A. D. 1993.

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

SANDOZ AGRO, INC.

1100 EAST TOLUENE AVENUE, DES PLAINES, ILLINOIS 60018

SANDOZ

CORPORATE HEADQUARTERS

TEL 708.699.1616

December 9, 1993

Mr. George LaRocca PM-13
Document Processing Desk (CERT)
Office of Pesticide Programs - H7505C
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460-001

Dear Mr. LaRocca:

Our overseas affiliates are requesting verification of U.S.
registration for the following product:

Fluvalinate Technical

EPA Reg. No.
55947-104

In order for us to complete the documentation, a certificate of
registration letter bearing the EPA seal is needed from your
office.

Because of continual requests for the same products, could you
please provide us with three copies of this certificate.

When the papers are ready, please give me a call at 708/390-3822.
I will arrange to have someone from our office pick them up.

Thank you for your assistance in this matter.

Sincerely,
SANDOZ AGRO, INC.

Cathy Elmi

Catherine Elmi
Supervisor, State Registrations

CAE/vo

Post-It - brand fax transmittal memo 7671		# of pages » 1	
To	George La Rocca	From	Catherine Elmi
Co.	US EPA	Co.	Sandoz
Dept.		Phone #	
Fax #	703-305-6596	Fax #	708-390-3941

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 26 1993

346 5405900
17/23

Mr. Jeff W. Popp
Registration Specialist II
Regulatory Affairs
SANDOZ AGRO, INCORPORATION
1300 East Touhy Avenue
Des Plaines, Illinois 60018

Dear Mr. Popp:

Subject: Revised Confidential Statement of Formula (CSF)
PR Notice 91-2 and Label Revision
FLUVALINATE Technical
EPA Registration Number 55947-104
Your Resubmission Dated April 16, 1993

The revised CSF and labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended is acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling

- ★ Delete the word "Trees." This is too broad and could imply forest trees. The current site descriptor "indoor and out door ornamental plantings" already includes ornamental trees.

Submit five (5) copies of your final printed labeling before you release the product for shipment.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure:

CONCURRENCES

SYMBOL	H7505C						
SURNAME	Allegretti						
DATE	5.26.93						

MAY 26 1993

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No. 55947-104

 **SANDOZ**

FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

(α RS,2R)-fluvalinate [(RS- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl) anilino]-3-methyl-
butanoate]* 87.2%

INERT INGREDIENTS: 12.8%

Total ... 100.0%

*U.S. Pat. 4,260,633 & 4,411,912

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA.
DO NOT BREATHE FUMES

EPA Reg. No. 55947-104

EPA Est. No. 55947-TX-1

Refer to analytical label on this
drum for exact analysis of this lot.

NET CONTENTS:

245 Kg (540 lbs.)

LOT NO.: _____

Specific gravity: 1.29

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand or sleeve-to-face exposure.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, estuaries, oceans or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your Regional Office of the Environmental Protection Agency.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE

Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food or feed.

DISPOSAL

Wastes resulting from the use of Fluvalinate Technical may be disposed of on site or at any approved waste disposal facility.

Metal Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES

Flush eyes with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED

Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN

Wash with plenty of soap and water.

PHYSICAL/CHEMICAL HAZARD

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

Only for formulation into an insecticide for the following use(s): other manufacturing use products, turf, trees, indoor and outdoor ornamental plantings and landscapes. Uses for which U.S. Environmental Protection Agency has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and uses for experimental purposes that are in compliance with U.S. Environmental Protection Agency Requirements.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Sandoz Agro, Inc.

LIMITATION OF WARRANTY AND LIMITATION OF LIABILITY

Notice: Read this Limitation of Warranty and Limitation of Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Sandoz or seller. All such risks shall be assumed by buyer or user.


Sandoz warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, under normal use conditions, subject to the risks described above. Sandoz makes no other express or implied warranty of fitness or of merchantability or any other express or implied warranty.

In no event shall Sandoz or seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. The exclusive remedy of the user or buyer, and the exclusive liability of Sandoz or seller for any and all claims, losses, injuries or damages (including claims based on breach of warranty, contract, negligence, tort, strict liability or otherwise) resulting from the use or handling of this product, shall be the return of the purchase price of the product or, at the election of Sandoz or seller, the replacement of the product.

Sandoz and seller offer this product, and buyer and user accept it, subject to the foregoing limitations of warranty and limitation of liability, which may not be modified by any oral or written agreement.

 **SANDOZ**
SANDOZ AGRO, INC.
1300 EAST 104TH AVENUE, DES PLAINES, ILLINOIS 60018

©1993 SANDOZ AGRO, INC.
8600101-20-AE

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number 163293
	Application for Pesticide:		
	Section I		

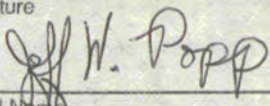
1. Company/Product Number SANDOZ/55947-104	2. EPA Product Manager G. LAROCCA	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SANDOZ/FLUVALINATE TECHNICAL	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) SANDOZ AGRO, INC. 1300 EAST TOUHY AVENUE DES PLAINES, IL 60018 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 55947-104 Product Name FLUVALINATE TECHNICAL	

Section II	
<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 2/14/90 & 11/9/92 <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

COMPANY NAME WAS CHANGED ON THE LABEL TO REFLECT NEW CORPORATE NAME.

Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit Package wgt. _____ No. per container _____	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package wgt. _____ No. per container _____	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) of Retail Container 245 KG. (540 LBS.)	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other (_____)	

Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name JEFF W. POPP	Title REGISTRATION SPECIALIST II	Telephone No. (Include Area Code) (708) 390-3734	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title REGISTRATION SPECIALIST II		
4. Typed Name JEFF W. POPP	5. Date April 16, 1993		

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 29 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Fluvalinate Technical, EPA Reg. No. 55947-104.
Proposed Change in Nomenclature. Sandoz Agro Letter
Dated 10/19/94.

DP Barcode: D209046. CBTS # 14669.

FROM: Michael T. Flood, Ph.D., Chemist
Acting Branch Senior Scientist
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

Michael T. Flood

THROUGH: Richard A. Loranger, Ph.D.
Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

R. Loranger

TO: George LaRocca/Adam Heyward, PM 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

Conclusion and Recommendation

CBTS has no objection to use of tau-fluvalinate on Sandoz label to refer to half resolved fluvalinate. The IUPAC name is also acceptable.

Detailed Considerations

In a letter dated 10/19/94, Sandoz Agro, Inc. proposes to change the name of "fluvalinate" in U.S. registrations to "tau-fluvalinate". This name has appeared on registrations in Europe since 1989 and reflects the half resolved form of fluvalinate. It is an approved ISO, ANSI and BSI name. Racemic fluvalinate consists of four isomers (SS+SR+RS+RR). Half resolved fluvalinate consists of two isomers. CBTS agrees that the name of "tau-fluvalinate" is a useful means of distinguishing the half resolved fluvalinate from the completely racemic mixture. We therefore have no objection to its adoption as the more specific name.

On its current labels, Sandoz uses the chemical nomenclature



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

"(α -RS,2R)-fluvalinate {(RS)- α -cyano-3-phenoxybenzyl (R)-2{2-chloro-4-(trifluoromethyl)anilino}-3-methyl-butanoate}. As the company notes, this nomenclature is recognized and acceptable to reflect the half resolved nature of tau-fluvalinate. However, to make the nomenclature compatible with registrations in other countries, Sandoz proposes to change its nomenclature to the IUPAC name {(RS)- α -cyano-3-phenoxybenzyl N-(2-chloro- α,α,α -trifluoro-p-tolyl)-D-valinate}. The IUPAC name appears in the January 1994 Update of the *Agrochemicals Handbook*, the *Farm Chemicals Handbook*, 1994, *The Pesticide Manual*, 1991, *BSI News*, April, 1989. Again, CBTS has no objection to the proposed change in chemical name.

cc: SF, RF, Circu., List B Rereg. File, Mike Flood
RDI: Acting Branch Chief:RALoranger:11/22/94.

CORPORATE HEADQUARTERS

TEL. 708.699.1616

April 16, 1993

Mr. George LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460

SUBJECT: FLUVALINATE TECHNICAL
EPA Registration Number 55947-104
US EPA Requested Label Changes

Dear Mr. LaRocca:

Please find enclosed for your acceptance the requested five (5) copies of our final printed labeling incorporating required changes. I would appreciate it greatly if I could receive an EPA stamped approved copy of this label from you for our records.

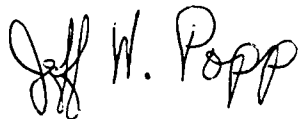
In your correspondence dated 11/9/92, in reply to Mrs. Hillebold's 10/15/91 label amendment notice, you accepted our amendments providing that we make a few label changes. Concerning item #1, the first paragraph under the heading "Directions for Use" was replaced with the form stated in your letter (which follows part V of PR 91-8). Concerning item #2, the requested revision of our label's container disposal statement to reflect the products metal drum storage was made. Concerning item #3, I consulted our Quality Assurance people about your question that our Lower Certified Limits cannot be lower than 84.6%. The limits we are certifying on our CSF are based on \pm four (4) standard deviations (approx. 5.0%) around the nominal concentration from a five batch analysis of technical fluvalinate and are due to the variable nature of our current manufacturing process. Thus, we are standing by our 5/22/91 CSF's certified limits and cite 40 CFR 158.175 (c) parts 1-4 as support.

In addition, our company logo was changed throughout the label to reflect our current corporate name.

Mr. George LaRocca
Page 2 of 2
April 16, 1993

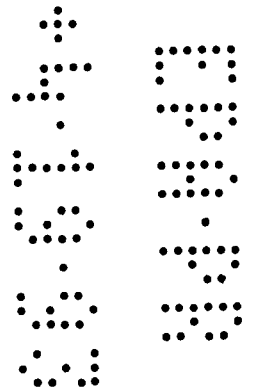
If you have any questions concerning the above label changes please feel free to call me at (708) 390-3734.

Sincerely,
SANDOZ AGRO, INC.



Jeff W. Popp
Registration Specialist II
Regulatory Affairs

JWP/vc
Enclosures



PRODUCT CHEMISTRY REVIEW

TO: PM _____ FROM: Reviewer: INDIRA GAIKOLA Date: 01/17/92
 EPA REG. NO.: 55947-104 PRODUCT NAME: FILVALINATE TECHNICAL

FOOD USE () INERTS CLEARED: C (), D (), E () NON FOOD USE ()
 21 CFR PARTS 170-199: () TOXIC INERTS LIST 1 (), 2 ()

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry data for your product. ☐ If submitted earlier, provide MRID Number(s). ☐ Your product is not sufficiently similar to the product you referenced.

2. ☒ In reference to the Confidential Statement of Formula (CSF), please provide the following:

- ☐ a) pH of product or pH at a specified water dilution.
- ☐ b) Density of product.
- ☐ c) Flash point of product.
- ☐ d) Flash point of product with propellant as per item #6(q) or item #5(c).
- ☐ e) Flame extension of product including flashbacks if noted.
- ☐ f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.
- ☐ g) The upper and lower certified limits of the individually added inerts.
- ☐ h)
- ☐ i)
- ☐ j)

3. ☒ Based on the current CSF dated 05/22/91, your product will ~~not~~ meet the label claim for the active ingredient. ~~Please revise the label or the CSF so that the information agrees.~~

The Registrant has submitted for an amended CSF + Label for this Technical. The previous label + CSF were 85.0% of active ingredient, and the amended CSF + Label are for 87.2% of ai. As per Product Chemistry Guidelines Series 61-2 for TGA1, the registrant has referred to MRID # 41889702. On examining this information, we find entire data of 5 batch analyses of the amended technical as stated above, entire manufacturing process and impurities as stated in the amended C.S.F. are included. Hence the Product Chemistry Review Section has no objection in accepting the proposed amendment.

PRODUCT CHEMISTRY REVIEW (cont'd)

4. ☐ Provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

- 1.
- 2.
- 3.
- 4.
- 5.

The supplier may contact EPA directly referencing the File Symbol or EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are not food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

- ☐ a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with ☐ PR Notice 84-1 for non-aerosol containers for houses and institutional uses or ☐ PR Notice 83-3 for all other uses.
- ☐ b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h)(2)(iii).
- ☐ c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellants).
- ☐ d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.
- ☐ e) Add a footnote to the inert ingredients indicating: Contains aromatic petroleum distillates, xylene or xylene-range aromatic solvent.
- ☐ f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

Do not use this product in or on electrical equipment
due to the possibility of shock hazard.

The variances are very wide for the limits
if nominal is 87.2 LCL can't be lower
than 84.6.

BO
1/21/92

Anna

DP BARCODE: D190597

CASE: 052150
SUBMISSION: S439651

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/23/93
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 346 RESUBMISSION
CHEMICALS: 109302 Fluvalinate

85.0000%

ID#: 055947-00104 FLUVALINATE TECHNICAL

COMPANY: 055947 SANDOZ AGRO, INC.

PRODUCT MANAGER: 13 GEORGE LARocca

703-305-6100 ROOM: CM2 204

PM TEAM REVIEWER: ADAM HEYWARD

703-305-5021 ROOM: CM2 206

RECEIVED DATE: 04/19/93

DUE OUT DATE: 07/18/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 190597 EXPEDITE: N DATE SENT: 04/23/93 DATE RET.: / /

CHEMICAL: 109302 Fluvalinate

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 06/07/93

CSF: Y

LABEL: Y

ASSIGNED TO DATE IN DATE OUT

DIV : RD / / / /

BRAN: RSB / / / /

SECT: PCRS / / / /

REVR : *Anna Skapars* / / / /

CONTR: *4-28-93* / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

Attached for your review response from Sandoz regarding
revised CSF,

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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DP BARCODE: D190597

CASE: 052150
SUBMISSION: S439651

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/23/93
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 346 RESUBMISSION
CHEMICALS: 109302 Fluvalinate

85.0000%

ID#: 055947-00104 FLUVALINATE TECHNICAL

COMPANY: 055947 SANDOZ AGRO, INC.

PRODUCT MANAGER: 13 GEORGE LARocca

703-305-6100

ROOM: CM2

204

PM TEAM REVIEWER: ADAM HEYWARD

703-305-5021

ROOM: CM2

206

RECEIVED DATE: 04/19/93

DUE OUT DATE: 07/18/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 190597

EXPEDITE: N

DATE SENT: 04/23/93

DATE RET.: / /

CHEMICAL: 109302 Fluvalinate

DP TYPE: 001 Submission Related Data Package

MIN DUE DATE: 06/07/93

CSF: Y

LABEL: Y

ASSIGNED TO DATE IN DATE OUT

DIV : RD

/ /

/ /

BRAN: RSB

/ /

/ /

SECT: PCRS

/ /

/ /

REVR :

/ /

/ /

CONTR:

/ /

/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Attached for your review response from Sandoz regarding
revised CSF,

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

344 / 5439651
23

CORPORATE HEADQUARTERS

TEL. 708.699.1616

April 16, 1993

Mr. George LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460

SUBJECT: FLUVALINATE TECHNICAL
EPA Registration Number 55947-104
US EPA Requested Label Changes

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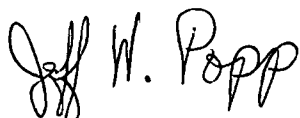
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Mr. George LaRocca
Page 2 of 2
April 16, 1993

If you have any questions concerning the above label changes please feel free to call me at (708) 390-3734.

Sincerely,
SANDOZ AGRO, INC.

A handwritten signature in cursive script that reads "Jeff W. Popp".

Jeff W. Popp
Registration Specialist II
Regulatory Affairs

JWP/vc
Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV - 9 1992

3455405900
17 9/28/92

Mrs. Donna M. Hillebold
Registration Specialist II
Regulatory Affairs
SANDOZ AGRO, INCORPORATION
1300 East Touhy Avenue
Des Plaines, Illinois 60018

Dear Mrs. Hillebold:

Subject: Revised Confidential Statement of Formula (CSF)
PR Notice 91-2 and Label Revision
FLUVALINATE Technical
EPA Registration Number 55947-104
Your Amended Application Dated October 15, 1991

The revised CSF and labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended is acceptable, provided that you make the following labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. In accordance with PR Notice 91-8, under the heading **"Directions For Use"** replace the first paragraph with following paragraph:

"Only For Formulation Into An Insecticide For The Following Use (s): (fill in blank with only those uses that are being supported by you the MP registrant.) Use For Which U.S. Environmental Protection Agency Has Accepted The Required Data And/Or Citations Of Data That The Formulator Has Submitted In Support Of Registration; And Uses For Experimental Purposes That Are In Compliance With U. S. Environmental Protection Agency Requirements."

2. Based on your application for pesticide registration dated April 30, 1983, this product is being stored in metal drums or containers. Therefore your container disposal statement must be revised to read as follows:

"Metal Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

CONCURRENCES							
SYMBOL							
SURNAME	Allegretti						
DATE	11-16-92						

3. In regard to your revised CSF, the variations appears to be larger than normal for the limits of nominal concentration, which is 87.2%. The Lower Certified Limits can not be lower than 84.6%.

Submit five (5) copies of your final printed labeling before you release the product for shipment.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure:

FLUVALINATE TECHNICAL

**AN INSECTICIDE-ACARICIDE
FOR MANUFACTURING USE ONLY**

ACTIVE INGREDIENT:

(α RS,2R)-fluvalinate [(RS- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl)anilino]-3-methyl-
butanoate]*.....87.2%

INERT INGREDIENTS:.....12.8%

TOTAL.....100.0%

*U.S. Pat. 4,260,633 & 4,411,912

EPA Reg. No. 55947-104
EPA Est. No. 55947-TX-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

**OPEN CONTAINER IN WELL VENTILATED AREA.
DO NOT BREATHE FUMES**

**REFER TO ANALYTICAL LABEL ON THIS DRUM FOR EXACT ANALYSIS OF THIS
LOT.**

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand- or sleeve-to-face exposure.

**SANDOZ CROP PROTECTION CORPORATION
1300 East Touhy Avenue
Des Plaines, Illinois 60018**

**NET CONTENTS: 245 Kg (540 lbs.)
Lot No.: _____
Specific gravity: 1.29**

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

IFLUTECA.91A

NOV - 9 1992

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No. 162

55947-104

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, estuaries, oceans or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your Regional Office of the Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the Formulators Manual for formulating instructions and other technical information. Formulators using this product are responsible for obtaining EPA Registration of their formulated product.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Sandoz Crop Protection Corporation.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food or feed.

DISPOSAL: Wastes resulting from the use of Fluvalinate Technical may be disposed of on site or at any approved waste disposal facility.

Triple rinse container (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

LIMITATION OF WARRANTY AND LIMITATION OF LIABILITY

NOTICE: Read this Limitation of Warranty and Limitation of Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Sandoz or seller. All such risks shall be assumed by buyer or user.

Sandoz warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, under normal use conditions, subject to the risks described above. SANDOZ MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

In no event shall Sandoz or seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SANDOZ OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SANDOZ OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Sandoz and seller offer this product, and buyer and user accept it, subject to the foregoing limitations of warranty and limitation of liability, which may not be modified by any oral or written agreement.

PRODUCT CHEMISTRY REVIEW

TO: PM _____ FROM: Reviewer: INDIRA GAIKOLA Date: 01/17/92
 EPA REG. NO.: 55947-104 PRODUCT NAME: FILVALINATE TECHNICAL

FOOD USE () INERTS CLEARED: C (), D (), E () NON FOOD USE ()
 21 CFR PARTS 170-199: () TOXIC INERTS LIST 1 (), 2 ()

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry data for your product. ☐ If submitted earlier, provide MRID Number(s). ☐ Your product is not sufficiently similar to the product you referenced.
2. ☒ In reference to the Confidential Statement of Formula (CSF), please provide the following:
 - ☐ a) pH of product or pH at a specified water dilution.
 - ☐ b) Density of product.
 - ☐ c) Flash point of product.
 - ☐ d) Flash point of product with propellant as per item #6(q) or item #5(c).
 - ☐ e) Flame extension of product including flashbacks if noted.
 - ☐ f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.
 - ☐ g) The upper and lower certified limits of the individually added inerts.
 - ☐ h)
 - ☐ i)
 - ☐ j)

3. ☒ Based on the current CSF dated 05/22/91, your product will ~~not~~ meet the label claim for the active ingredient. ~~Please revise the label or the CSF so that the information agrees.~~

The Registrant has submitted for an amended CSF + Label for this Technical. The previous label + CSF were 85.0% of active ingredient, and the amended CSF + Label are for 87.2% of ai. As per product Chemistry Guidelines Series 61-2 for TGA1, the registrant has referred to MRID # 41889702. On examining this information, we find entire data of 5 batch analyses of the amended technical as stated above, entire manufacturing process and impurities as stated in the amended C.S.F. are included. Hence the Product Chemistry Review Section has no objection in accepting the proposed amendment.

PRODUCT CHEMISTRY REVIEW (cont'd)

4. ☐ Provide the chemical identity of all components, the percentage composition, CAS Registry Number, and Material Safety Data Sheet (two copies) for the following compounds:

- 1.
- 2.
- 3.
- 4.
- 5.

The supplier may contact EPA directly referencing the File Symbol or EPA Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are not food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

- ☐ a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with ☐ PR Notice 84-1 for non-aerosol containers for houses and institutional uses or ☐ PR Notice 83-3 for all other uses.
- ☐ b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h)(2)(iii).
- ☐ c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellants).
- ☐ d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.
- ☐ e) Add a footnote to the inert ingredients indicating: Contains aromatic petroleum distillates, xylene or xylene-range aromatic solvent.
- ☐ f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

Do not use this product in or on electrical equipment
due to the possibility of shock hazard.

The variances are very wide for the limits
if nominal is 87.2 LCC can't be lower
than 84.6.

BC
1/21/92

PRODUCT CHEMISTRY REVIEW

TO: PM _____ FROM: Reviewer: INDIRA GAIKOLA Date: 01/17/92
 EPA REG. NO.: 55947-104 PRODUCT NAME: FILVALINATE TECHNICAL

FOOD USE () INERTS CLEARED: C (), D (), E () NON FOOD USE ()
 21 CFR PARTS 170-199: () TOXIC INERTS LIST 1 (), 2 ()

Please provide the requested information for the following checked items:

1. ☐ Submit the product specific product chemistry data for your product. ☐ If submitted earlier, provide MRID Number(s). ☐ Your product is not sufficiently similar to the product you referenced.
2. ☒ In reference to the Confidential Statement of Formula (CSF), please provide the following:
 - ☐ a) pH of product or pH at a specified water dilution.
 - ☐ b) Density of product.
 - ☐ c) Flash point of product.
 - ☐ d) Flash point of product with propellant as per item #6(q) or item #5(c).
 - ☐ e) Flame extension of product including flashbacks if noted.
 - ☐ f) The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.
 - ☐ g) The upper and lower certified limits of the individually added inerts.
 - ☐ h)
 - ☐ i)
 - ☐ j)

3. ☒ Based on the current CSF dated 05/22/91, your product will ~~not~~ meet the label claim for the active ingredient. ~~Please revise the label or the CSF so that the information agrees.~~

The Registrant has submitted for an amended CSF + Label for this Technical. The previous label + CSF were 85.0% of active ingredient, and the amended CSF + Label are for 87.2% of ai. As per product Chemistry Guidelines Series 61-2 for TGA1, the registrant has referred to MRID # 41889702. On examining this information, we find entire data of 5 batch analyses of the amended technical as stated above, entire manufacturing process and impurities as stated in the amended CSF are included. Hence the product Chemistry Review Section has no objection in accepting the proposed amendment.

SANDOZCROP PROTECTION

Sandoz Crop Protection Corporation

Corporate Headquarters
1300 East Touhy Avenue
Des Plaines, Illinois 60018
708.699.1616

October 15, 1991

Mr. George LaRocca
Document Processing Desk (Amend)
Office of Pesticide Programs H7504C
U.S. Environmental Protection Agency
401 M. Street (SW)
Washington, D.C. 20460

Subject: LABEL AMENDMENT: PERCENT ACTIVE INGREDIENT
FLUVALINATE TECHNICAL
EPA REGISTRATION NUMBER 55947-104

Dear Mr. LaRocca:

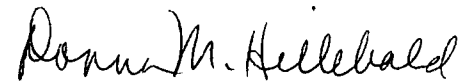
According to PR Notice 91-2, the Agency has now established the nominal concentration as the only acceptable label claim for the amount of active ingredient in a product. Submitted with this letter and amendment form are five copies of the amended label for FLUVALINATE TECHNICAL (55947-104). The percent active and inert ingredients have been revised to reflect the most recent CSF (attached) and five batch analyses (MRID #41889702).

A copy of the February 14, 1990 stamped label has been included for reference purposes. Changes requested by the Agency have been incorporated in the proposed label and are shaded for your convenience. Please note that the warranty statement has also been revised.

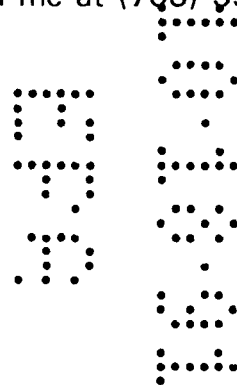
If you require further information regarding this label, please call me at (708) 390-3796.

Sincerely,

SANDOZ CROP PROTECTION CORPORATION

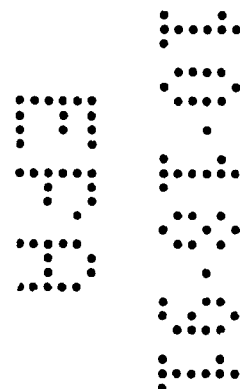

Donna M. Hillebold
Registration Specialist II
Regulatory Affairs

DMH/ps



T A B S

Cover Letter	TAB 1
Pesticide Application Form No. OMB No. 2070-0060	TAB 2
Confidential Statement of Formula (5/22/91)	TAB 3
February 14, 1990 EPA Stamped Label	TAB 4
One Copy Amended Label (Revisions Shaded)	TAB 5
Five Copies Amended Label (No Shading)	TAB 6



(A)



United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

163219

Section I

1. Company/Product Number 55947-104	2. EPA Product Manager G. LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) FLUVALINATE TECHNICAL	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Sandoz Crop Protection Corporation 1300 East Touhy Avenue Des Plaines, Illinois 60018 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Percent active and inert ingredients have been changed per PR Notice 91-2. Revisions in Environmental Hazards Statement, subheading of Statement of Practical Treatment, subheading of Precautionary Statement and Formulators statement per 2/14/90 EPA letter. New Warranty Statement

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
	If "Yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	<input type="checkbox"/> Plastic	
			No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 245 kg (540 lbs)		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other (_____)	

* Certification must be submitted.

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Donna M. Hillebold	Title Registration Specialist II	Telephone No. (Include Area Code) (708) 390-3796

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature <i>Donna M. Hillebold</i>	3. Title Registration Specialist II	6. Date Application Received (Stamped) 171
4. Typed Name Donna M. Hillebold	5. Date October 15, 1991	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

345 - AH - Chem

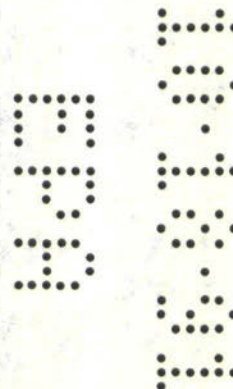
LABEL AMENDMENT

FLUVALINATE TECHNICAL

55947-104

**SANDOZ CROP PROTECTION CORPORATION
1300 EAST TOUHY AVENUE
DES PLAINES, IL 60018**

OCTOBER 15, 1991



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

300,5394518
38122

JUL 16 1991

Mrs. Donna M. Hillebold
Registration Specialist
Regulatory Affairs
SANDOZ CROP PROTECTION Corporation
Corporate Headquarters
1300 East Touhy Avenue
Des Plaines, Illinois 60018

Dear Mrs. Hillebold:

Subject: **SECTION 6(A)2 SUBMISSION-ACUTE CONTACT TOXICITY
STUDY WITH HONEY BEES**
Fluvalinate Technical (Case #2295)
EPA Registration Number 55947-104
Your Submission Dated February 11, 1991

We have completed a review of the honey bee acute toxicity study submitted under section 6(a)2 for fluvalinate technical. This study is scientifically sound, and shows fluvalinate to be highly toxic to honey bees. In an acute contact test, the LD50 was determined to be approximately 0.2 micrograms per bee.

It is unclear as to how the submitted study derived an LD50 in the "highly toxic" category. Our records up to now showed that fluvalinate to be no more than "moderately toxic" to bees. Due to the disparity in test results between previous bee toxicity studies and the subject study, we are requiring you to repeat the study. We will defer our comments/label recommendations until the new study is submitted and reviewed. We understand you already intend to repeat the study. Please provide us your time frame for submission of this study.

CONCURRENCES							
SYMBOL	H7505C						
SURNAME	A. Raymond						
DATE	7/15/91						

EPA Form 1320-1 (12-70) *U.S.GPO:1989-624-485/10186 OFFICIAL FILE COPY 174

For detailed considerations, please refer to the enclosed
EPA Ecological Effects Branch review dated June 28, 1991.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

enclosure:

cc: Ernie Dobbins

DP BARCODE: D163592

CASE: 052150
SUBMISSION: S394518

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/16/91
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 405 DATA-ADVERSE DATA
CHEMICALS: 109302 N-Ü2-Chloro-4-trifluoromethyl)phenyl§-DL-valine (+ 85.0000%

ID#: 055947-00104 FLUVALINATE TECHNICAL
COMPANY: 055947 SANDOZ CROP PROTECTION CORPORATION
PRODUCT MANAGER: 15 GEORGE LARocca 703-557-2400 ROOM: CM#2 204
PM TEAM REVIEWER: ADAM HEYWARD 703-557-4421 ROOM: CM#2 200
RECEIVED DATE: 02/11/91 DUE OUT DATE: 04/22/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 163592 EXPEDITE: Y DATE SENT: 04/16/91 DATE RET.: / /
CHEMICAL: 109302 N-Ü2-Chloro-4-trifluoromethyl)phenyl§-DL-valine (+-)-cyano(
TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 05/11/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	04/16/91	04/16/91
BRAN: EEB	/ /	JUL / 1 / 99
SECT: IO	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the attached adverse data as it relates to
non-target insects (Honey Bees).

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 1 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Fluvalinate 6(a)2 Submission: Acute
Toxicity Study with Honey Bees

FROM: *for* James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) *Douglas J. Wilson 6/28/91*

TO: George LaRocca, PMT-15
Insecticide/Rodenticide Branch
Registration Division (H7505C)

EEB has reviewed the honey bee acute toxicity study submitted under 6(a)2 for fluvalinate technical. The study showed fluvalinate to be highly toxic to honey bees, with an LD50 of 0.2 micrograms per bee.

The record on fluvalinate has consistently shown this chemical to be no more than "moderately toxic" to bees. Results of several studies place fluvalinate in the "practically nontoxic" range. Consistent with this record is the fact that fluvalinate (Apistan) has been used extensively to control Varroa mites within bee hives in the U.S. and Europe, apparently without significant adverse effects on the bees.

EEB cannot offer an explanation as to how the submitted study derived an LD50 in the "highly toxic" range. However, Sandoz Corp. has stated its intent to have the test redone this summer. EEB will defer comment on the present submission, pending receipt of data from this new study.

Any questions or comments on this memo should be referred to Allen Vaughan at 557-0464.

Attachments



Printed on Recycled Paper

DATA EVALUATION RECORD

1. Chemical: Fluvalinate
2. Test Material: Technical, 88.4% ai
3. Study Type: Honey bee acute contact LD50

Species tested: Apis mellifera

4. Study ID: Winter, P.A., K.A. Hoxter, and G.J. Smith. 1991.
Fluvalinate Technical: An acute contact toxicity study
with the honey bee. Wildlife International Ltd.
Project No. 131-142. Submitted by Sandoz Crop
Protection Corp., Des Plaines, Illinois. EPA Acc. No.
417839-01.

5. Reviewed By:

Allen W. Vaughan
Entomologist
EEB/EFED

Signature: Allen W. Vaughan
Date: 5.16.91

6. Approved By

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 5.16.91

7. Conclusions:

This study is scientifically sound, and shows fluvalinate to be highly toxic to honey bees. In an acute contact test, the LD50 was determined to be approximately 0.2 micrograms per bee. This study fulfills the guideline requirement for an acute contact toxicity test on honey bees.

8. Recommendations: N/A
9. Background: This study was submitted as 6(a)2 data.
10. Discussion of Individual Tests: N/A

11. Materials and Methods:

Four days prior to initiation of the study, one frame containing honey bee pupae was selected from Wildlife International's hives. The frame was placed in an automatic incubator for four days to allow adult emergence. All test bees were 1 to 4 days old at test initiation, and were apparently healthy. On the day of study initiation, all bees that had emerged were immobilized with N₂, and at least 25 bees were placed into each of two replicate test chambers.

Test chambers were rolled paper containers. Each container was covered with a plastic petri dish through which a glass vial containing 50% sugar water was inserted. This food source was available to the test bees throughout the study.

The photoperiod was eight hours of light per day. Test temperatures ranged from 22 to 23° C.

Eight treatment levels, 0.00625, 0.0125, 0.025, 0.05, 0.1, 0.2, 0.4, and 0.6 micrograms per bee, were tested along with a solvent control and a negative control. Two replicates were tested at each dosage, with 25 bees per replicate. The solvent control bees received a volume of acetone equal to the largest volume used during the test.

Recently collected bees were immobilized with N₂ to facilitate handling. Each bee was individually dosed with the appropriate test solution. Solvent control bees were dosed with acetone.

Observations on mortality and signs of toxicity were made twice on the day of initiation and once on Day 1 and Day 2 after dosing.

Mortality data were analyzed using the computer program of C.E. Stephan. In this study the binomial probability method was used.

12. Reported Results:

The study authors found that fluvalinate was highly toxic to honey bees, with an LD50 of 0.2 ug per bee.

13. Study Authors' Conclusions/ QA Measures

48-hr. LD50 = 0.2 ug per bee (highly toxic).

14. Reviewer's Discussion and Interpretation of the Study

A. Test Procedures: Procedures were in accordance with protocols recommended in the guidelines. There were no problems in this regard.

B. Statistical Analysis: Independent validation by EEB confirms that the analysis is appropriate and supports the conclusions of the study.

C. Discussion/Results: Fluvalinate is highly toxic to honey bees.

D. Adequacy of Study:

1. Classification: Core

2. Rationale: Guidelines protocol

3. Reparability: N/A

15. Completion of One-Liner for Study: N/A

16. CBI Appendix: N/A

SANDOZCROP PROTECTION

Sandoz Crop Protection Corporation

Corporate Headquarters
1300 East Touhy Avenue
Des Plaines, Illinois 60018
708.699.1616

February 11, 1991

Mr. George LaRocca
Document Processing Desk
Office of Pesticide Programs H7504C
U.S. Environmental Protection Agency
401 M. Street (SW)
Washington, D.C. 20460

Subject: Fluvalinate Technical (Case #2295)
EPA Reg. No. 55947-104
Section 6(a)2 Submission
Acute Contact Toxicity Study With Honey Bee

Dear Mr. LaRocca:

Pursuant to FIFRA Section 6(a)2 requirements, enclosed is a final report for a recently conducted acute contact toxicity bee study. The study was conducted as part of the Phase 3 reregistration process for fluvalinate (Reregistration Case #2295) because the original data did not meet the criteria check list. The results of this study indicate that fluvalinate technical, as a solution in acetone, is highly toxic to honeybees.

This result is quite surprising because all previous bee studies conducted with the technical material as well as with formulated product have shown fluvalinate to be practically non-toxic to bees.

In order to further evaluate the results reported in this study, we requested the expert opinion of Dr. D. Bassand. Dr. Bassand is the head of our insecticide research and is an expert in our Witterswil, Switzerland center. A copy of his opinion is enclosed with this letter.



Mr. George LaRocca
Re: Fluvalinate Technical
February 11, 1991
Page two

We consider the reported results as non-representative of the real situation. We believe that in the stressful environment described in the attached correspondence, that an unusually high level of susceptibility to fluvalinate was observed. Furthermore, the lack of a positive control does not allow for the validation of the study by comparing fluvalinate to other insecticides.

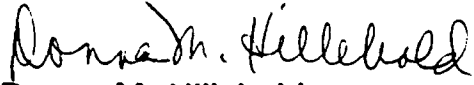
Because of all the inherent uncertainties associated with these results and the preponderance of existing data with consistently quite different findings, we will be re-conducting the study this summer. In the interim we do not see any reason to modify current label language since we already have some restrictive statements which adequately protect foraging bees. In the event you disagree with this tactic, please contact me.

Three copies of the acute toxicity bee study conducted by Wildlife International, Ltd. and Dr. Bassand's expert opinion are enclosed as part of this submission. Also included is the appropriate transmittal document.

If you should require further information regarding this submission please call me at (708) 390-3796.

Sincerely,

SANDOZ CROP PROTECTION CORPORATION


Donna M. Hillebold
Registration Specialist
Regulatory Affairs

DMHG:ps
enclosures

cc: Ernie Dobbins, OPP/EPA

bcc: J. Atkin
S.M. Chen
C. Elmi
R. Fresh

FILE: Fluv. 55947-104
OPP File #7a



x-file: CRAC 1991 Fluv. Tech.

TRANSMITTAL DOCUMENT

Name and Address of Submitter

Sandoz Crop Protection Corporation
1300 East Touhy Avenue
Des Plaines, Illinois 60018

417839-00

Regulatory Action

6(a)2 Submission: Fluvalinate Technical
55947-104
Reregistration Case #2295

Transmittal Date

February 11, 1991

List of Submitted Studies

158.590 NON-TARGET INSECT DATA REQUIREMENTS

41783901 <Volume 1: Wildlife International Ltd. (1991)
Fluvalinate Technical: An Acute
Contact Toxicity Study with the
Honey Bee. Project No. 131-142
Guideline No. 141-1.

Donna M. Hillebold 2/11/91 708/390-3796
Donna M. Hillebold Date Telephone
Registration Specialist
Sandoz Crop Protection Corporation

TRANSMITTAL DOCUMENT

Name and Address of Submitter

Sandoz Crop Protection Corporation
1300 East Touhy Avenue
Des Plaines, Illinois 60018

Regulatory Action

6(a)2 Submission: Fluvalinate Technical
55947-104
Reregistration Case #2295

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Guideline No. 141-1.

Donna M. Hillebold 2/11/91 708/390-3796
Donna M. Hillebold Date Telephone
Registration Specialist
Sandoz Crop Protection Corporation

From: CLVAX::CLVAX::MRGATE::"A1::BASSAND_D"
 To: CHISTC::KEEFER
 Subject: Fluvalinate: Bee toxicity

From: NAME: Denis Bassand
 FUNC:
 TEL: <BASSAND_D@A1@CLVAX>
 To: NAME: CHARLIE KEEFER <KEEFER AT CHISTC AT MRGATE>
 CC: NAME: Godfrey Teal <TEAL_G@A1@CLVAX>,
 NAME: John Atkin <PAPER MAIL@A1@CLVAX>

Charlie,

These are my comments to the report from Wildlife International Ltd.:

Table 1, page 13, last column: % mortality should have been corrected for "natural" mortality in the negative control, as follows:

Concentration (ug/bee)	% Mortality	Corrected % Mortality
Negative Control	6	0
0.00625	0	0
0.0125	6	0
0.025	2	0
0.05	12	6
0.1	12	6
0.2	48	45
0.4	68	66
0.6	58	55

Clearly, there is a poor dose-response, 0.0125 ug/bee and 0.4 ug/bee being more active than the next higher dose, and with the three highest doses, 0.2, 0.4 and 0.6 ug/bee producing responses close to 50%. This is an indication that the bee population was not homogeneous.

Using Logit analysis, I made estimates of the regression parameters and compared them with those obtained in a test carried out in 1989 in Witterswil under GLP (BLK-Nr.: 77'265):

	Maryland 1990	Witterswil 1989
Chi(2) test for heterogeneity:	15.22 (sig.)	0.965 (non-sig).
df:	6	3
b (slope) +- standard-error:	3.02 +- 0.62	6.44 +- 1.05
LD50 +- Standard-error:	0.34 +- 0.07	6.70 +- 0.62
Coefficient of variation:	21%	9%

Chi(2) test for homogeneity is significant (at the 5% level) for the Maryland data, indicating that the bee population was not homogeneous in its response to the action of fluvalinate. The regression coefficient b (slope) of the Maryland trial is smaller than that of the Witterswil trial, expressing a weaker response to the dose in the American trial. The greater heterogeneity of the Maryland bee population is also reflected by the coefficient of variation, which is more than two times greater than that of Witterswil.

This heterogeneity, as well as the enhanced fluvalinate susceptibility of the Maryland bees, might be due to different stress-inducing factors, which negatively influenced the bees during the test. According to the test description, there are several factors, which might have unfavorably affected the bees:

- The containers (ca. 9 cm in diameter and 9 cm high): this is too small to enclose 25 bees, which will be very crowded. Moreover, as described, the containers seem to be quite airtight, preventing proper gas exchange.
- The volume administered: 2 microlitre per bee is a very large amount (twice the volume usually applied in Witterswil and elsewhere!)
- The photoperiod, eight hours per days, was too short. Such short-day conditions may considerably affect the physiology of the bees.
- The ambient temperatures, 22 to 23 degrees Centigrade, were certainly sub-optimal for the bees

Moreover, these factors might have interacted to result in a severe stress of the bees, expressed by an unusually high level of susceptibility to fluvalinate. In this connection, the absence of any toxic and non-toxic standard is especially unfortunate.

Finally, a look at previous tests, carried out by Atkins in Riverside or by myself in Witterswil, clearly shows, that the obtained LD50 for fluvalinate are always greater than 4 microgram per bee:

LD50 (ug/bee)		
Fluvalinate HR (techn. grade)	18.43	Atkins (1981)
Mavrik 2E	8.43	Atkins (1983)
Mavrik 2F	9.12	Atkins (1983)
Mavrik 2E	8.43	Bassand (1983)
Mavrik 2E	4.70	Bassand (1984)
Fluvalinate HR (techn. grade)	6.70	Donat (1989)

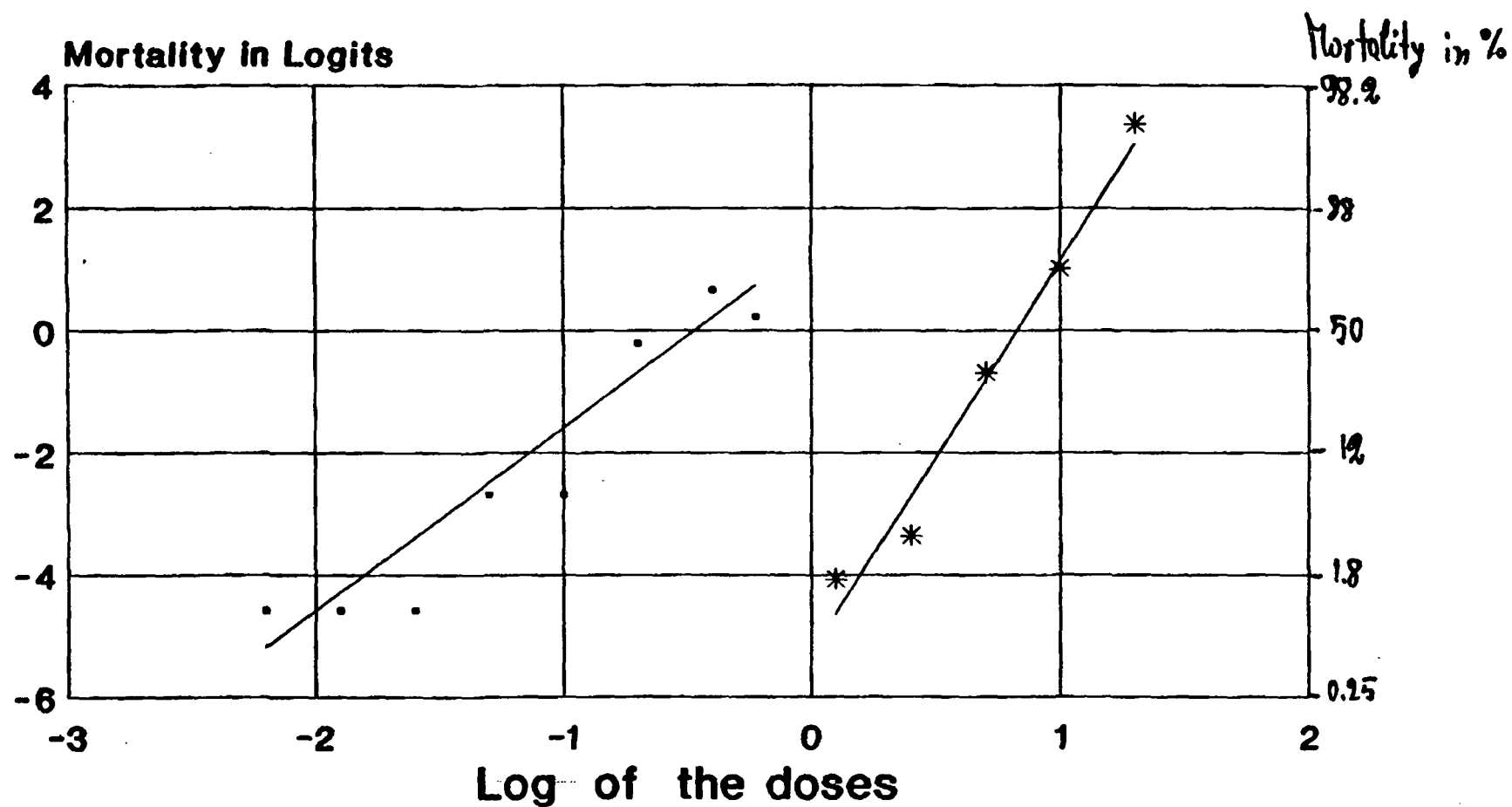
Field trials in France have also established the complete innocuity of fluvalinate for bees. On the other hand, fluvalinate is registered and used in France, in USA, and in other countries for the control of the Varroa mites in beehives. In this application, fluvalinate never caused any observable trouble to bee colonies.

In my opinion, the data generated by Wildlife International Ltd are not representative of the real situation. I strongly suggest to repeat these tests in 1991, possibly with another, more reliable company, or in Witterswil, in June or July.

With my best regards

D. Bassand

Bee Toxicity of Fluvalinate HR



• Maryland 1990 * Witterswil 1989

✓R

SANDOZCROP PROTECTION

Sandoz Crop Protection Corporation

Corporate Headquarters
1300 East Touhy Avenue
Des Plaines, Illinois 60018
708.699.1616

February 11, 1991

Mr. George LaRocca
Document Processing Desk
Office of Pesticide Programs H7504C
U.S. Environmental Protection Agency
401 M. Street (SW)
Washington, D.C. 20460

Subject: Fluvalinate Technical (Case #2295)
EPA Reg. No. 55947-104
Section 6(a)2 Submission
Acute Contact Toxicity Study With Honey Bee

Dear Mr. LaRocca:

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In order to further evaluate the results reported in this study, we requested the expert opinion of Dr. D. Bassand. Dr. Bassand is the head of our insecticide research and is an expert in our Witterswil, Switzerland center. A copy of his opinion is enclosed with this letter.



Mr. George LaRocca
Re: Fluvalinate Technical
February 11, 1991
Page two

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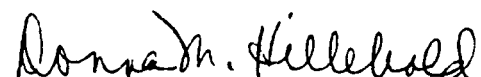
Because of all the inherent uncertainties associated with these results and the preponderance of existing data with consistently quite different findings, we will be re-conducting the study this summer. In the interim we do not see any reason to modify current label language since we already have some restrictive statements which adequately protect foraging bees. In the event you disagree with this tactic, please contact me.

Three copies of the acute toxicity bee study conducted by Wildlife International, Ltd. and Dr. Bassand's expert opinion are enclosed as part of this submission. Also included is the appropriate transmittal document.

If you should require further information regarding this submission please call me at (708) 390-3796.

Sincerely,

SANDOZ CROP PROTECTION CORPORATION


Donna M. Hillebold
Registration Specialist
Regulatory Affairs

DMHG:ps
enclosures

cc: Ernie Dobbins, OPP/EPA

bcc: J. Atkin
S.M. Chen
C. Elmi
R. Fresh

FILE: Fluv. 55947-104
OPP File #7a



x-file: CRAC 1991 Fluv. Tech.

TRANSMITTAL DOCUMENT

Name and Address of Submitter

Sandoz Crop Protection Corporation
1300 East Touhy Avenue
Des Plaines, Illinois 60018

Regulatory Action

6(a)2 Submission: Fluvalinate Technical
55947-104
Reregistration Case #2295

Transmittal Date

February 11, 1991

List of Submitted Studies

158.590 NON-TARGET INSECT DATA REQUIREMENTS

Volume 1: Wildlife International Ltd. (1991)
Fluvalinate Technical: An Acute
Contact Toxicity Study with the
Honey Bee. Project No. 131-142
Guideline No. 141-1.

Donna M. Hillebold 2/11/91 708/390-3796
Donna M. Hillebold Date Telephone
Registration Specialist
Sandoz Crop Protection Corporation



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FILE COPY

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Ms. Donna M. Hillebold
Registration Specialist
Sandoz Crop Protection
Corporate Headquarters
1300 East Touhy Avenue
Des Plaines, Illinois 60018

FEB 14 1990

Yellow
COPY

Dear Ms. Hillebold:

Subject: Label Amendment - Change Name, Address, Registration Number
and Warranty Statement
FLUVALINATE Technical
EPA Registration Number 55947-104
Your Application of January 24, 1990

The labeling referred to above, submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Note: The following label changes must be made at your next printing of final labeling.

1. The environmental hazard statement must be revised to read as follow: "This product is highly toxic to fish or other aquatic organisms. Do not discharge effluent containing this product directly into lakes, streams, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your state Board or Regional Office of the Environmental Protection Agency"

2. Change the statement of practical treatment subheading to read, "STATEMENT OF PRACTICAL TREATMENT". In addition, the statement concerning eye treatment should be revised to read: "Flush eyes with plenty of water. Get medical attention if irritation persists".

3. The precautionary statement subheading must read as follow:

PRECAUTIONARY STATEMENT
HAZARD TO HUMAN AND DOMESTIC ANIMALS
WARNING

4. Add the statement, "Formulators using this product are responsible for obtaining EPA Registration of their formulated product".

Sincerely,

A handwritten signature in black ink, appearing to read "G. T. LaRocca", written in a cursive style.

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

SANDOZ CROP PROTECTION

FLUVALINATE TECHNICAL

AN INSECTICIDE-ACARICIDE FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

(α RS, 2R)-fluvalinate [(RS- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl) anilino]-3-methyl-
butanoate]* 85.0%

INERT INGREDIENTS: 15.0%
Total ... 100.0%

*U.S. Pat. 4,260,633 & 4,411,912

HAZARDS TO HUMANS

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA.
DO NOT BREATHE FUMES

EPA Reg. No. 55947-104
EPA Est. No. 55947-TX-1

NET CONTENTS:
245 Kg (540 lbs.)

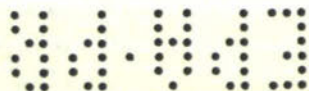
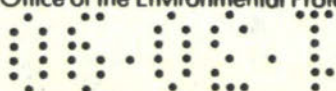
Refer to analytical label on this
drum for exact analysis of this lot.

LOT NO.: _____
Specific gravity: 1.29

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand or sleeve-to-face exposure.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency.



ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 14 1990

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

RONK GRAPHICS LTD

55947-104

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

STORAGE

Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food or feed.

DISPOSAL

Wastes resulting from the use of Fluvalinate Technical may be disposed of on site or at any approved waste disposal facility.

Triple rinse container (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

FIRST AID

IF IN EYES

Flush with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED

Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN

Wash with plenty of soap and water.

PHYSICAL/CHEMICAL HAZARD

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the Formulators Manual for formulating instructions and other technical information.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Sandoz Crop Protection Corporation.

LIMITED WARRANTY AND LIABILITY

NOTICE: Read this Limited Warranty and Liability before opening or using this product. If terms are not acceptable, return it at once, unopened.

It is critical that this product be used and mixed only as specified on the label. The laws of a State may make some or all of this paragraph inapplicable or may give you rights hereunder. Except to the extent prohibited by law, the exclusive remedy of the user or buyer and the limit of liability of this Company or any other Seller for any and all losses, personal injuries or damages resulting from the use of this product shall be the purchase price paid by the user or buyer for the quantity of product involved. Except to the extent prohibited by State law, there is no warranty, and this Company and other Sellers disclaim all liability losses, personal injury or damages: (i) arising from any use of this product in a manner or for a purpose not recommended in its label directions, or from mixing this product before use with any substance except as recommended by the product's label; (ii) arising from handling or storage in violation of label instructions; (iii) for all indirect, special or consequential damages; (iv) when not reported to this Company within one year of discovery; and (v) arising from product not used within the label designated shelf life or four years from the date of purchase, whichever occurs first. THERE ARE NO IMPLIED WARRANTIES AND NO WARRANTIES OF MERCHANTABILITY OR FITNESS.



SANDOZ
CROP PROTECTION
CORPORATION
DELLANDER 6 00010

©SANDOZ CROP PROTECTION CORP. 1988
8600101-20-AC

SANDOZCROP PROTECTION

Sandoz Crop Protection Corporation

Corporate Headquarters
1300 East Touhy Avenue
Des Plaines, Illinois 60018

January 24, 1990

Office of Pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attn: G. LAROCCA

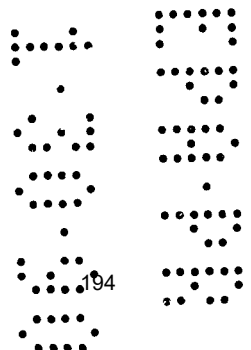
Subject: **LABEL AMENDMENTS FOR PRODUCTS CONTAINING
FLUVALINATE**

Dear Mr. LaRocca:

As you are probably aware, Sandoz Crop Protection Corporation has only been in existence since 1986. The company was created by the merger of Zoecon Corporation and Veisicol Chemical Corporation. As a result, many of the products have had more than one registration number. To complicate matters further, SCPC has relocated their corporate headquarters from Chicago to Des Plaines, Illinois. As you might guess, our labels have gone through many name, number and address changes in the recent past.

Included with this letter are the Application for Pesticide Amendment forms for five different products which contain fluvalinate as the active ingredient. In the past, various international authorities have had difficulty with certificates which do not have the current company name, address and registration number. While the numerous transfer letters pertaining to the products are included as explanation, our colleagues abroad encounter delays. Per my conversation with Adam Heyward, I am submitting these changes as amendments in order to have an EPA stamped copy of each label in our file.

None of these changes require data and as a result, Sandoz Crop Protection Corporation requests an expeditious review per PR Notice 89-2.



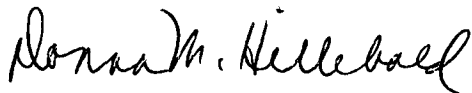
Page -2-

Mr. George LaRocca
U.S. Environmental Protection Agency
Subject: Label Notifications

Thank you for your cooperation in this matter. If you have any questions regarding this matter please call me at (708) 390-3796.

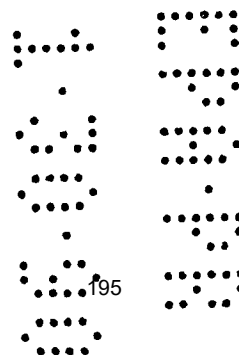
Sincerely,

SANDOZ CROP PROTECTION CORPORATION



Donna M. Hillebold
Registration Specialist
Regulatory Affairs

DMH:ps
enclosures





United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EXPEDITE

Application for Pesticide: ☐ Registration ☒ Amendment

OPP Identifier Number

131090

Section I

1. Company/Product Number 55947-104	2. Date January 23, 1990	3. Product Manager G. LaRocca	4. Proposed Classification <input checked="" type="checkbox"/> General <input type="checkbox"/> Restricted
--	-----------------------------	----------------------------------	---

5. Name and Address of Applicant (Include ZIP Code)

SANDOZ CROP PROTECTION CORPORATION
1300 EAST TOUHY AVENUE
DES PLAINES, ILLINOIS 60018

☒ Check if this is a new address

6. Product Name

FLUVALINATE TECHNICAL

Section II - Amendment Information

1. Subject	Date of Letter
<input type="checkbox"/> Resubmission in response to Agency letter <input type="checkbox"/> Final printed label in response to Agency letter <input checked="" type="checkbox"/> Other (explain below)	

Minor amendment to change name, address, registration number and warranty statement on EPA stamped approved label.

Section III

1. Material This Product Will Be Packaged In		2. Type of Container	
Child-Resistant Packaging	Unit Packaging	Water-Soluble Packaging	<input checked="" type="checkbox"/> Metal
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Plastic
	If "Yes,"	If "Yes,"	<input type="checkbox"/> Glass
	Unit package wgt No. per container	Package weight No. per container	<input type="checkbox"/> Paper
			<input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information		4. Size(s) of Retail Container	
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	245 kg (540 lbs)		
5. Location of Label Directions		6. Manner in Which Label Is Affixed To Product	
<input checked="" type="checkbox"/> On Label	<input type="checkbox"/> Lithograph <input type="checkbox"/> Other (Specify)		
<input type="checkbox"/> On material accompanying product	<input checked="" type="checkbox"/> Paper glued		
	<input type="checkbox"/> Stenciled		

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name

DONNA M. HILLEBOLD

Title

Registration Specialist

Telephone No. (Include Area Code)
(708) 390-3796

6. Date Application Received
(Stamped)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title

Registration
Specialist

4. Typed Name

Donna M. Hillebold

5. Date Signed

1/24/90

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mockup labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
6. EPA Use Only.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. M. O. Messerschmidt
Sandoz Crop Protection Corp.
341 East Ohio Street
Chicago, IL 60611

JAN 6 1987

Dear Mr. Messerschmidt:

Subject: Transfer of Pesticide Registrations From
Company Number 11273 & 20954, to 55947

Pursuant to Zoecon's requests in their letters of September 2, 1986, and December 5, 1986, we have approved the transfer of the following registrations from Zoecon Corporation, company numbers 11273 & 20954 to Sandoz Crop Protection Corp., company number 55947.

The effective date of these changes is January 2, 1987.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
THIOVIT	11273-1	55947-48
Thuricide HP Potency Aqueous Concentrate	11273-2	55947-49
Thuricide HP Spray Concentrate	11273-3	55947-50
Thuricide (R) HP 1.5 B* Dust Base	11273-4	55947-51
Thuricide HP 90M Dust	11273-5	55947-52
Thuricide HP Cornmeal Bait	11273-6	55947-53
Thuricide HP 144M Dust	11273-8	55947-54
Technical Norflurazon	11273-10	55947-55
Thuricide HP 16B Aqueous Concentrate	11273-11	55947-56
EVITAL	11273-12	55947-57
Zorial 80 WP	11273-13	55947-58
Elgar Biological Insecticide	11273-17	55947-59
Thuricide 400 M Granules	11273-18	55947-60
Solicam 80 WP Herbicide	11273-19	55947-61
Thuricide 32B	11273-23	55947-62
Telok 80 WP	11273-24	55947-63
Noloc Concentrate	11273-27	55947-64
Noloc Bait Formulation	11273-28	55947-65
Thuricide 24B	11273-29	55947-66
Solicam Flowable Herbicide	11273-32	55947-67
Noloc Concentrate 1 X 10	11273-33	55947-68
Thuricide 32LV	11273-35	55947-69

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
Thuricide Dust	11273-36	55947-70
Zorial Flowable Herbicide	11273-37	55947-71
Solicam Flowable Herbicide	11273-39	55947-72
Solicam Granular Herbicide	11273-41	55947-73
Thuricide 48LV	11273-42	55947-74
Thuricide 64 LV Plus	11273-43	55947-75
Thuricide 64 LV	11273-44	55947-76
Zorial DF Dry Flowable Herbicide	11273-47	55947-77
Solicam Dry Flowable Herbicide	11273-48	55947-78
San 415 SC 32 LV	11273-49	55947-79
Laser LC Microbial Insecticide Concentrate	11273-50	55947-80
Laser WP Microbial Insecticide Concentrate	11273-51	55947-81
Enstar 5E Insect Growth Regulator	20954-4	55947-82
Oil Spray	20954-63	55947-83
Best Pentac 50 WP	20954-80	55947-84
ZIPP 16-5-8 Turf Feed With Balan	20954-82	55947-85
ZIPP Lawn Food With Chinch Bug Control	20954-83	55947-86
ZIPP Turf Food 15-5-10 Weed & Feed	20954-84	55947-87
Apex 5E	20954-89	55947-88
Dormant Spray	20954-91	55947-89
Methoprene Technical, An Insect Growth Regulator for Formulating Use Only	20954-92	55947-90
Do-It Yourself Rose and Ornamental Pest Control	20954-98	55947-91
Do-It Yourself Garden Pest Control	20954-99	55947-92
Minex 5E	20954-102	55947-93
Altosid 5E-FZ-515	20954-104	55947-94
Pentac WP	20954-106	55947-95
Pentac (Technical)	20954-108	55947-96
Pentac Aqua - Flow Miticide	20954-112	55947-97
Mavrik 2E Insecticide	20954-115	55947-98
ZPA - 1426	20954-118	55947-99
F2-515-0100	20954-122	55947-100
Mavrik Aquaflow (TM)	20954-123	55947-101
Fluvalinite 25% Bulk (EC)	20954-124	55947-102
Fluvalinate 80% Concentrate, An Insecticide for Manufacturing Use Only	20954-125	55947-103
Fluvalinite Technical, An Insect- icide for Manufacturing Use Only	20954-126	55947-104
Mavrik 2F Insecticide/Acaricide	20954-127	55947-105
Fluvanate 22.3% k F Bulk	20954-129	55947-106
Technical Sathon 10-10	20954-131	55947-107
Sathon 10-10 Miticide 50% Wettable Powder	20954-132	55947-108
S-Methoprene Technical	10954-135	55947-109
Pentac Miticide Mist	20954-137	55947-110

In response to Zoecon's letter of December 5, 1986, 20954-101 has not been transferred. Please note that we do not transfer distributor registrations. New applications for supplemental registrations must be submitted by the new registrant.

In order for the supporting data for the above products to be transferred, EPA must be provided with the date the data was submitted, the type of data, the EPA accession number of the data, if known, and the active ingredients for the subject products. If the transferor's rights to all data for a particular active ingredient are transferred, the transferor should state whether his or her company name should be deleted from the data submitters list for that chemical.

Please note that the following products are pending registration with EPA and cannot be marketed in interstate commerce until they have been registered.

<u>Product Name</u>	<u>Old EPA File Symbol</u>	<u>New EPA File Symbol</u>
Telok Granular	11273-UA (46)	55947-RRR (111)
Oxadixyl Technical	11273-LE (52)	55947-RRE (112)
Sandofan 31F	11273-LU (54)	55947-RRG (113)
Evisect 50SP	11273-LL (55)	55947-RRU (114)
Pentac Miticide Mist Concentrate	20954-RGI (138)	55947-RRL (115)

The following Experimental Use Permits (EUPs) have been transferred. Their expiration dates have not changed.

<u>EUP Name</u>	<u>Old EPA File Symbol</u>	<u>New EPA File Symbol</u>
SAN 518F/Potatoes (renewal pending)	11273-EUP-33	55947-EUP-4
SAN 518F/Tomatoes (pending)	11273-EUP-GT	55947-EUP-L
SAN 410I Potatoes (pending)	11273-EUP-UN	55947-EUP-A
SAN 506F Potatoes/Tomatoes (pending)	11273-EUP-UG	55947-EUP-T
Zorial Peanuts exp. 4/9/88	11273-EUP-44	55947-EUP-8
SPUR 22EW	20954-EUP-33	55947-EUP-9

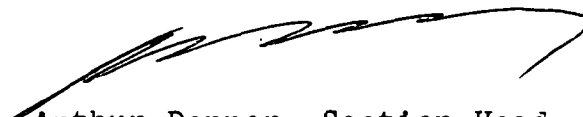
The following Experimental Use Permits have expired and cannot be transferred.

<u>EUP Name</u>	<u>Old EPA File Symbol</u>
Mavrik 2E exp. 5/15/86	20954-EUP-19
Mavrik 2E exp. 9/17/86	20954-EUP-27
SPUR 22EW exp. 9/17/86	20954-EUP-28
SPUR 22EW exp. 5/15/86	20954-EUP-29
SAN 810I 4.5TB 300 exp. 8/30/86	20954-EUP-30
SAN 810I 4WG 303 exp. 8/30/86	20954-EUP-31
SAN 310I 4WG 301 exp. 8/30/86	20954-EUP-32
SAN 810I 4WG 302 exp. 8/30/86	20954-EUP-33

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

By copy of this letter we are informing Zoecon Corporation of these changes.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Arthur Donner', with a long, sweeping horizontal stroke extending to the right.

Arthur Donner, Section Head
Registration Support and
Emergency Response Branch
Registration Division (TS 767-C)

cc: Zoecon Corporation

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

200 136723
38 2

DEC 14 1984

Ms. L. E. Staiger
Zoecon Corporation
975 California Avenue
Palo Alto, CA 94304

Dear Ms. Staiger:

Subject: Fluralinate Technical
EPA Registration No. 20954-126
Your Letter of November 14, 1984

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely yours,

Timothy A. Gardner
Product Manager-17
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Enclosure

RD/DIS:JOB:51442:Gardner:sah:RD-57:12/11/84:Kenderick & Co., 898-1270:Del.12/20/84

CONCURRENCES							
SYMBOL ▶							
SURNAME ▶							
DATE ▶							

PRODUCT
CODE

6100-00

FLUVALINATE

TECHNICAL

AN INSECTICIDE-ACARICIDE FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

(α RS,2R)-fluvalinate [(RS- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl) anilino]-3-methyl-
butanoate)*..... 85%

INERT INGREDIENTS:..... 15%

* U.S. Pat. 4,260,633 & 4,411,912

Refer to analytical label on this drum
for exact analysis of this lot.

Lot

No: _____

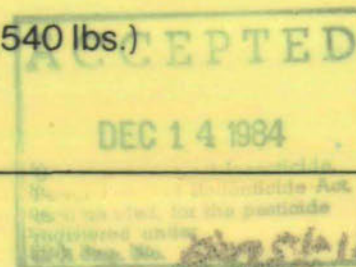
Specific gravity: 1.29

NET CONTENTS: 245 Kg (540 lbs.)

EPA Registration No. 20954-126

EPA Est. No. 1258-NY-3

MADE IN USA



HAZARDS TO HUMANS WARNING

OPEN CONTAINER IN WELL VENTILATED AREA. DO NOT BREATHE FUMES

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse. Sensitive persons may temporarily experience an itching, burning sensation, with or without a rash, following exposure. Avoid hand or sleeve-to-face exposure.

24 Hour Emergency Phone Response (415) 857-0172 (collect).

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

Storage: Store away from direct sunlight or heat. Pesticides must be stored in a secured area away from other products, food or feed.

Disposal: Wastes resulting from the use of Fluvalinate Technical may be disposed of on site or at any approved waste disposal facility.

Triple rinse container (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, by other procedures approved by State and local authorities.

FIRST AID

If in eyes: Flush with plenty of water. Get medical attention if irritation persists.

If swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If on skin: Wash with plenty of soap and water.

PHYSICAL/CHEMICAL HAZARD

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Refer to the Formulators Manual for formulating instructions and other technical information.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Zoecon Corporation.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemical description on the label. Zoecon makes no other warranty, express or implied.

Manufactured by:



Zoecon Corporation, a Sandoz Company
Crop Protection Division

Zoecon Corporation
A Sandoz Company

975 California Avenue, Palo Alto, California 94304
P.O. Box 10975, Palo Alto, California 94303

November 14, 1984

Mr. Timothy Gardner PM-17
Insecticide/Rodenticide Branch
Registration Division TS-767C
U.S. Environmental Protection Agency
Crystal Mall Bldg. #2, Room 207
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: Fluvalinate Technical, an Insecticide for Manufacturing Use Only
EPA Reg. No. 20954-126

Dear Mr. Gardner:

Enclosed please find five (5) copies of the final printed label for the above product. These are being submitted as part of the conditions required for registration of Fluvalinate Technical.

Should you have any questions regarding this product do not hesitate to contact me.

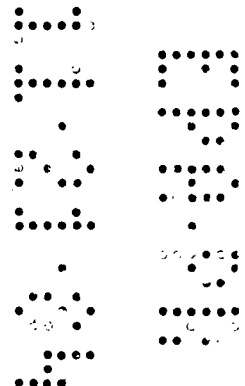
Sincerely,

Luana E. Staiger

Luana E. Staiger
Registration Specialist

dje
enclosures

0148p



Zoecon Industries
12200 Denton Drive
Dallas TX 75234

300 /
38 /

I, Timothy A. Gardner, Product Manager 17, Insecticide-Rodenticide Branch, Registration Division, Office of Pesticide Programs, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, do hereby certify that the pesticide product listed below is currently registered with this Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, that the label attached is a true, correct, and compared copy of the correspondence of record, and that the product may be sold and marketed in the United States of America for the uses indicated on the label.

The product registration listed below has been issued to:

Zoecon Industries
12200 Denton Drive
Dallas TX, 75234

EPA Registration Number

20954-126

Name of Product

Fluvalinate

IN WITNESS WHEREOF

I have hereunto set my hand
and affixed the seal of the
U.S. Environmental Protection
Agency this 19th day of June, 1984.

Timothy A. Gardner

Zoecon Industries

June 14, 1984

Mr. Timothy Gardner (PM-17)
Insecticide-Rodenticide Branch
Registration Division (TS-767)
U.S. Environmental Protection Agency
Crystal Mall, Bldg. 1
1921 Jefferson Davis Hwy.
Arlington, VA 22202

RE: Registration Certification Letters

Dear Mr. Gardner:

Please prepare 5 letters certifying the following product is currently registered with the Environmental Protection Agency and that the enclosed product label is a true, correct and compared copy of the correspondence of record. These certification letters will be used in support of international regulatory clearance and thus it is imperative that they have the Agency's official seal and be on EPA letterhead.

<u>EPA Reg. Number</u>	<u>Product Name</u>	<u>Use</u>	<u>Active Ingredient</u>
20954-126	Fluvalinate Technical	Pesticide	Fluvalinate

This product will be offered for sale under the basic registered label rather than as a supplemental distributor label. For your convenience in reviewing the product label, I have included a copy of the EPA registered label. Also included is an example of the certification letter needed.

Would you please return the certification letters to my attention in Dallas by Federal Express. I have enclosed a self-addressed Federal Express air bill and envelope. The local Federal Express dispatch telephone number is 691-1901. Federal Express requires one (1) hour access time for pick up.

Thank you in advance for your assistance in processing this request. If you have any questions or if additional information could be furnished by Zoecon to expedite this request, please contact either Gary Clark or me at 214/243-2321.

Sincerely,
ZOECON INDUSTRIES
A Division of Zoecon Corporation

Susan Brotherton

Susan Brotherton
Regulatory Specialist

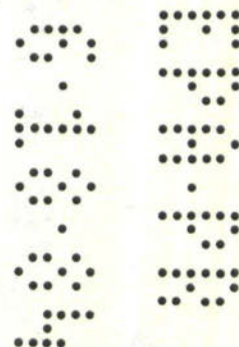
SB:sw

Enclosures

MAILING ADDRESS: 12200 Denton Drive • Dallas, Texas 75234 • (214) 243-2321

CORPORATE ADDRESS: 12000 Ford Road • Dallas, Texas 75234

Telex #730775



FLUVALINATE TECHNICAL

An Insecticide-Acaricide For Manufacturing Use Only

ACTIVE INGREDIENT:

(α RS,2R)-fluvalinate [(RS)- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl)anilino]-3-methyl-
butanoate]* 85%

INERT INGREDIENTS: 15%

Lot No: _____

Specific Gravity: 1.29 g/cc

Refer to analytical label on this drum for exact analysis of this lot.

*U.S. PAT. 4,260,633 and other Patents Pending.

EPA Registration No. 20954-

EPA Est. No. 1258-NY-3

ACCEPTED
VIA AIRMAIL
12 MAY 1988

100% 100%

HAZARDS TO HUMANS

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA
DO NOT BREATHE FUMES

20954-126

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse.

FIRST AID

IF IN EYES: Flush with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 qt. 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency.

PHYSICAL/CHEMICAL HAZARD

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

Pesticide Disposal: Pesticide or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resources Conservation and Recovery Act.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the Formulators Manual for formulating instructions and other technical information.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Zoecon Corporation.

WARRANTY AND CONDITIONS OF SALE

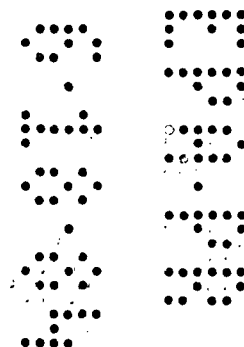
Zoecon Corporation warrants that this product conforms to the chemical description on the label. Zoecon makes no other warranty, express or implied.

ZOECON CORPORATION
AGRICULTURAL CHEMICALS DIVISION
Palo Alto, California 94304

MADE IN USA

NET CONTENTS: 258 Kg (569 lbs.)

68-6100-14 RO
(0399E)



300
38

ZOECON Industrials
12200 Denton Drive
Dallas TX, 75234

I, Timothy A. Gardner, Product Manager 17, Insecticide-Rodenticide Branch, Registration Division, Office of Pesticide Programs, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, do hereby certify that the pesticide product listed below is currently registered with this Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, that the label attached is a true, correct, and compared copy of the correspondence of record, and that the product may be sold and marketed in the United States of America for the uses indicated on the label.

The product registration listed below has been issued to:

Zoecon Industries
12200 Denton Drive
Dallas TX, 75234

EPA Registration Number

20954-126

Name of Product

Fluvalinate Technical

IN WITNESS WHEREOF

I have hereunto set my hand
and affixed the seal of the
U.S. Environmental Protection
Agency this 1st day of June, 1984.

Timothy A. Gardner

Zoecon Industries

January 31, 1984

Mr. Tim Gardner (PM-17)
U.S. Environmental Protection Agency
Crystal Mall, Bldg. 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

RE: Registration Certification Letters

Dear Mr. Gardner:

Please prepare 16 letters certifying the following product is currently registered with the Environmental Protection Agency and that the enclosed product label is a true, correct and compared copy of the correspondence of record. These certification letters will be used in support of international regulatory clearance and thus it is imperative that they have the Agency's official seal and be on EPA letterhead.

<u>EPA Reg. Number</u>	<u>Product Name</u>	<u>Use</u>	<u>Active Ingredient</u>
20954-126	Fluvalinate Technical	Pesticide	Fluvalinate

This product will be offered for sale under the basic registered label rather than as a supplemental distributor label. For your convenience in reviewing the product label, I have included a copy of the EPA registered label. Also included is an example of the certification letter needed.

Would you please return the certification letters to my attention in Dallas by Federal Express. I have enclosed a self-addressed Federal Express air bill and envelope. The local Federal Express dispatch telephone number is 691-1901. Federal Express requires one (1) hour access time for pick up.

Thank you in advance for your assistance in processing this request. If you have any questions or if additional information could be furnished by Zoecon to expedite this request, please contact either Gary Clark or me at 214/243-2321.

Sincerely,
ZOECON INDUSTRIES
A Division of Zoecon Corporation

Susan Brotherton

Susan Brotherton
Regulatory Specialist

SB:sw
Enclosures

MAILING ADDRESS: 12200 Denton Drive • Dallas, Texas 75234 • (214) 243-2321

CORPORATE ADDRESS: 12000 Ford Road • Dallas, Texas 75234

Telex #730775



FLUVALINATE TECHNICAL

An Insecticide-Acaricide For Manufacturing Use Only

ACTIVE INGREDIENT:

(α RS,2R)-fluvalinate [(RS)- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl)anilino]-3-methyl-
butanoate]* 85%

INERT INGREDIENTS: 15%

Lot No: _____

Specific Gravity: 1.29 g/cc

Refer to analytical label on this drum for exact analysis of this lot.

*U.S. PAT. 4,260,633 and other Patents Pending.

EPA Registration No. 20954-

EPA Est. No. 1258-NY-3

HAZARDS TO HUMANS

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA
DO NOT BREATHE FUMES

20954-126

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse.

FIRST AID

IF IN EYES: Flush with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency.

PHYSICAL/CHEMICAL HAZARD

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

Pesticide Disposal: Pesticide or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resources Conservation and Recovery Act.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the Formulators Manual for formulating instructions and other technical information.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Zoecon Corporation.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemical description on the label. Zoecon makes no other warranty, express or implied.

ZOECON CORPORATION
AGRICULTURAL CHEMICALS DIVISION
Palo Alto, California 94304

MADE IN USA

NET CONTENTS: 258 Kg (569 lbs.)

68-6100-14 RO
(0399E)

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (WH-567)
WASHINGTON, D.C. 20460

EPA REGISTRATION NO.

DATE OF ISSUANCE

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

NOTICE OF PESTICIDE:

☐ REGISTRATION
☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

Fluvalinate Technical, An Insecticide
Advice for Manufacturing Use Only

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Loxon Corporation
975 California Avenue
Palo Alto, CA 94304

160 | 97885
18

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(2)(B) provided that you:

1. Submit and/or file all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 20854-125."

b. Refer to IR Notice 83-3 in regard to the Storage & Disposal Statement.

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 3(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Timothy A. Gattner
Product Manager (17)
Insecticide-Fungicide Branch
Registration Division (WH-567)

Enclosure

☐ ATTACHMENT IS APPLICABLE

BEST DOCUMENT AVAILABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

FLUVALINATE TECHNICAL

An Insecticide-Acaricide For Manufacturing Use Only

ACTIVE INGREDIENT:

(α RS,2R)-fluvalinate [(RS)- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl)anilino]-3-methyl-
butanoate]* 85%

INERT INGREDIENTS: 15%

Lot No: _____

Specific Gravity: 1.29 g/cc

Refer to analytical label on this drum for exact analysis of this lot.

*U.S. PAT. 4,260,633 and other Patents Pending.

EPA Registration No. 20954-

EPA Est. No. 1258-NY-3

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 26 1983

HAZARDS TO HUMANS

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA
DO NOT BREATHE FUMES

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

20954-126

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse.

FIRST AID

IF IN EYES: Flush with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency.

PHYSICAL/CHEMICAL HAZARD

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

Pesticide Disposal: Pesticide or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resources Conservation and Recovery Act.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the Formulators Manual for formulating instructions and other technical information.

This product may not be used or referenced as a source of ingredient in the formulation, manufacture or registration of any products without prior written authorization from Zoecon Corporation.

WARRANTY AND CONDITIONS OF SALE

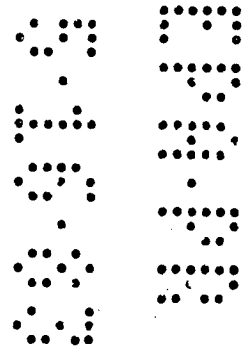
Zoecon Corporation warrants that this product conforms to the chemical description on the label. Zoecon makes no other warranty, express or implied.

ZOECON CORPORATION
AGRICULTURAL CHEMICALS DIVISION
Palo Alto, California 94304

MADE IN USA

NET CONTENTS: 258 Kg (569 lbs.)

68-6100-14 RO
(0399E)



July 12, 1983

Mr. Timothy A. Gardner (PM-17)
Insecticide - Rodenticide Branch
Registration Division (TS-767-C)
U.S. Environmental Protection Agency
Crystal Mall, Bldg. #2 RM 207
1921 Jefferson Davis Highway
Arlington, PA. 22202

Subject: Fluvalinate Technical, An Insecticide For Manufacturing Use Only
List of Data Requirements

Dear Mr. Gardner:

Zoecon Corporation hereby submits the enclosed List of Data previously submitted in support of registration of Fluvalinate Technical, An Insecticide for Manufacturing Use Only, as required by the Owner Submission Method of Data Requirements, described in PR Notice 83-4.

Please do not hesitate to call if you have any questions concerning this submission or any of the data listed here.

Sincerely,

Adrienne Ste. Marie

Adrienne Ste. Marie
Registration Specialist

-FLUVALINATE TECHNICAL, AN INSECTICIDE FOR MANUFACTURING USE ONLY

LIST OF DATA REQUIREMENTS

OWNER SUBMISSION METHOD

DATA REQUIREMENT	STUDY TITLE	DATE SUBMITTED	ACCESSION NUMBER	CONFIDENTIAL BUSINESS INFORMATION
<u>158.120 Product Chemistry</u>				
Product Identity	Fluvalinate Chemistry-Product Identity	2-4-82	070657	No
Analysis of Ingredient	Analysis of Chemical Impurities in Technical Fluvalinate	2-4-82	070657	Yes
Physical and Chemical Characteristics	Fluvalinate: Physical and Chemical Properties	2-4-82	070657	Yes
<u>158.125 Residue Chemistry</u>				
Chemical Identity	Proposed Label	4-30-83	—	No
Directions for Use	Proposed Label	4-30-83	—	No
<u>158.130 Environmental Fate</u>				
Degradation Studies-Lab:				
Hydrolysis	Hydrolytic Stability of Fluvalinate	2-4-82	070658	Yes
Photodegratation in Water	Photodegration of Fluvalinate	11-21-79	241389	Yes

*Conditional Data Requirement

FLUVALINATE TECHNICAL, AN INSECTICIDE FOR MANUFACTURING USE ONLY

LIST OF DATA REQUIREMENTS

OWNER SUBMISSION METHOD

DATA REQUIREMENT	STUDY TITLE	DATE SUBMITTED	ACCESSION NUMBER	CONFIDENTIAL BUSINESS INFORMATION
Metabolism Studies:				
Aerobic Soil	Aerobic Soil Metabolism of Fluvalinate	11-21-79	241389	Yes
Mobility Studies:				
Leaching	Degradation and Movement of Fluvalinate in Soil	2-8-83	250536	Yes
Dissipation Studies:				
Soil	Degradation and Movement of Fluvalinate in Soil	2-8-83	250536	Yes
<u>158.135 Toxicology</u>				
Acute Testing:				
Oral LD ₅₀ - Rat	Acute Oral Toxicity of ZR-3210 - Rat	2-4-82	070660	Yes
Dermal LD ₅₀	Acute Permal Toxicity-ZR-3210	5-8-81	070095	Yes
Inhalation LC ₅₀	See Footnote 1			
Primary Eye Irritation	Primary Eye Irritation-ZR-3210	11-21-79	241389	Yes
Primary Dermal Irritation	See Footnote 2			
Dermal Sensitization	See Footnote 2			
Acute Delayed Neurotoxicity - Hens	Acute Delayed Neurotoxicity in Hens with ZR-3210	5-8-81	070096	Yes

FLUVALINATE TECHNICAL, AN INSECTICIDE FOR MANUFACTURING USE ONLY

LIST OF DATA REQUIREMENTS

OWNER SUBMISSION METHOD

DATA REQUIREMENT	STUDY TITLE	DATE SUBMITTED	ACCESSION NUMBER	CONFIDENTIAL BUSINESS INFORMATION
Subchronic Testing:				
*21-Day Dermal-Rabbit	21-Day Dermal Toxicity Study in Rabbits with ZR-3210	2-4-83	070664	Yes
Chronic Testing:				
*Chronic Feeding-Dog	6-Month Subchronic Dog Study - ZR-3210	5-8-81	070098	Yes
*Teratogenicity-Rats	Teratology Study in Rats: ZR-3210	5-8-81	070097	Yes
*Teratogenicity-Rabbit	Rabbit Teratology Study of ZR-3210	2-4-82	070663	Yes
*Reproduction-Rat	Two-Generation Reproduction Study in Rats: ZR-3210	2-4-82	070096	Yes
Mutagenicity Testing:				
*Gene Mutation	Mutagenicity Evaluation of ZR-3210 in the Ames Salmonella/Microsome Plate Test	2-4-82	070664	Yes
*Chromosomal Aburation	Mutagenicity Evaluation of ZR-3210 in an invitro Cytogenetic Assay	11-21-79	241388	Yes
Special Testing:				
*Metabolism-Rat	Fluvalinate Metabolism by Rats	4-30-83	250142	Yes

FLUVALINATE TECHNICAL, AN INSECTICIDE FOR MANUFACTURING USE ONLY

LIST OF DATA REQUIREMENTS

OWNER SUBMISSION METHOD

DATA REQUIREMENT	STUDY TITLE	DATE SUBMITTED	ACCESSION NUMBER	CONFIDENTIAL BUSINESS INFORMATION
<u>158.145 Wildlife and Aquatic Organisms</u>				
Avian and Mammalian Testing:				
Avian Oral LD ₅₀	Acute Oral LD ₅₀ of Half-Resolved ZR-3210 in Bobwhite Quail	2-4-82	070665	Yes
Avian Dietary LC ₅₀	Eight Day dietary LC ₅₀ in Bobwhite Quail: ZR-3210	2-4-82	070665	Yes
*Avian Reproduction	One Generation Reproduction Study in Bobwhite Quail: ZR-3210	5-8-81	070100	Yes
Aquatic Organism Testing:				
Freshwater Fish LC ₅₀	Acute Toxicity of Fluvalinate Technical to Rainbow Trout	2-4-82	070665	Yes
Acute LC ₅₀ Freshwater Invertabrates	Dynamic Acute Toxicity of (^a RS, 2R) Fluvalinate Technical to the Water Flea (Daphnia Magna)	4-30-83	250141	Yes
*Acute LC ₅₀ Estuarine and Marine Organisms	Acute Toxicity of Fluvalinate Technical to Mysid Shrimp	4-30-83	250141	Yes
*Fish Early Life Stage	Early Life Stage Toxicity of Fluvalinate Technical to Fathead Minnows in a Flow Through System	4-30-83	250141	Yes
*Aquatic Inverta- brates Life Cycle	Chronic Toxicity of Fluvalinate Technical to Daphnia Magna under Flow Through Conditions	4-30-83	250141	Yes

FLUVALINATE TECHNICAL, AN INSECTICIDE FOR MANUFACTURING USE ONLY

LIST OF DATA REQUIREMENTS

OWNER SUBMISSION METHOD

DATA REQUIREMENT	STUDY TITLE	DATE SUBMITTED	ACCESSION NUMBER	CONFIDENTIAL BUSINESS INFORMATION
<u>158.155 Non-Target Insects</u>				
Honey Bee Acute Contact LD ₅₀	Bee Research Investigation with Fluvalinate Technical, 1982 Final Report	10-6-82	—	Yes
Honey Bee-Toxicity of Residues on Foliage	Bee Research Investigation with Fluvalinate Technical, 1982 Final Report	10-6-82	—	Yes

*Conditional Data Requirement

Footnote 1: Technical fluvalinate is an extremely viscous liquid which cannot be poured unless heated. Since aerosolization of technical fluvalinate and subsequent inhalation exposure is not possible, the acute inhalation study was not conducted.

Footnote 2: Due to the highly viscous nature of technical fluvalinate, it is not possible for human dermal exposure to occur via splashing or splattering, as with less viscous liquids. If skin exposure were to occur, it would be to a discrete glob of semi-solid material which could be removed by a rapid stream of water and would not remain on the skin. Maintaining prolonged contact between skin and the technical chemical in a laboratory test is an artificial situation, unrelated to potential human exposure. Accordingly, a separate test for primary dermal irritancy was not conducted. However irritation to directly exposed skin was assessed as one of two test endpoints of a total of four acute dermal toxicity studies with both rats and rabbits.

0541E

JUL 13 1983

MEMO TO FILE

Date JUL 25 1983

Fluralinate

(Chemical)

Zoecon Corporation

(Applicant)

20954-126

(Registration Number)

Registration

(Type of Action)

In Monsanto Co. v. Acting Administrator, EPA (E.D. Mo. No. 79-366c (1) Judge H. Kenneth Wangelin ruled, in an amended Judgement on May 9, 1983, that applications for pesticide registrations can be approved by EPA under Sections 3(c)(5) and 3(c)(7) of FIFRA in cases where the applicant has submitted to EPA, and relied solely upon, his own data to support his application for registration; provided that any applicant for registration must either submit its own data, or cite its own previously submitted data, or cite data that appears in the public literature, or cite the previously submitted data of another person with the prior written permission of such other person, and that EPA is precluded from considering or using any other data in support of any application for registration.

In response to the rulings in the NACA and Monsanto court cases the Agency, on June 16, 1983 issued PR Notice 83-4 announcing two interim procedures. First, the Owner Submission Method, by which applicants for registration or amended registration under section 3 of FIFRA may satisfy the statutory requirement to provide data to support their application. Under this method of support the applicant is required to (A) submit a list of data requirements applicable to his product, and (B) satisfy each data requirement either (1) by submitting (or citing) his own valid data (2) by citing valid data previously submitted to EPA by another, with the original submitted permission (3) by documenting that no data have previously been submitted which would meet the specific data requirement, or (4) by a combination of these. Applicants for registration of an end-use product electing to rely on the formulators exemption must submit with his list of data requirements a fully completed "FORMULATORS EXEMPTION STATEMENT" and must have on file with the Agency a current, complete, and accurate Confidential Statement of Formula or if the Confidential Statement of Formula is not current and accurate, must submit a new one.

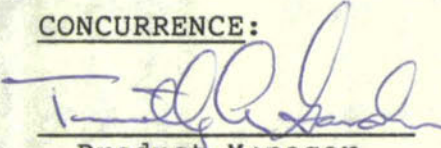
Second, the Permission of All Prior Data Submitters (or Total Permission) Method of Support, which an applicant may use rather than the Owners Submission Method, provided the applicant furnishes written permission from all data submitters who have furnished data which are relevant to support the applicant's product registration. This includes permission from everyone on the Agency's most recent data submitters list and any other data submitter the EPA identifies.

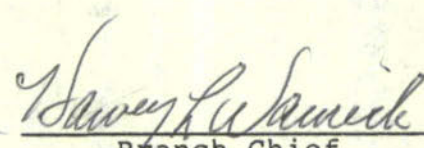
Therefore, to reasonably ensure compliance with the NACA and Monsanto judgments and PR Notice 83-4, a review of the items checked below has been conducted. The results of that review is summarized in the comment section of this memo.

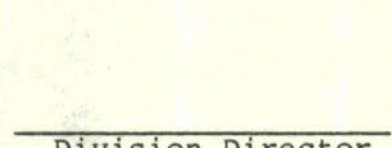
COMMENTS

- ☒ I. OWNERS SUBMISSION METHOD OF SUPPORT CHOSEN BY APPLICANT
- ☒ LIST OF DATA REQUIREMENTS (page 11, I, A)
 - ☒ LIST OF DATA SATISFYING ABOVE REQUIREMENTS (page 17, B)
 - ☐ PERMISSION LETTER(S) IF APPROPRIATE (page 11, I, 2 or 4)
 - ☐ FORMULATORS EXEMPTION FORM (83-4A page 1)
 - ☒ CONFIDENTIAL STATEMENT OF FORMULA (page 12, 2)
- ☐ II. TOTAL PERMISSION METHOD OF SUPPORT CHOSEN BY APPLICANT (83-4A page 15)
- ☐ PERMISSION FROM DATA SUBMITTER LIST COMPANIES
 - ☐ PERMISSION FROM OTHER SOURCES

This registration action is considered to be in compliance with the above judgment, and with PR Notice 83-4.

CONCURRENCE:

 Product Manager


 Branch Chief


 Division Director

REG.# 20954-REA Fluvalinate Technical MUP

Zoecon Corp.
975 California Ave.
Palo Alto, CA 94304

- 1) The submission contains data on the manufacturing process; analytical methods and results; and proposed use patterns. We have no adverse comments at this time. If, in future, food uses are proposed, HED will need to review this material. The basic chemical descriptions as presented are satisfactory, but we have seen no long term storage stability information. [Note to PM: is this information in a petition maybe ?]
- 2) Update storage and disposal statements.

Brinson Conerly IRB/TSS

B Conerly

6/24/83

April 30, 1983

Mr. Timothy A. Gardner (PM-17)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
U.S. - Environmental Protection Agency
Crystal Mall, Bldg. #2, Rm 207
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Subject: Fluvalinate Technical, An Insecticide for
Manufacturing Use Only
Application for Pesticide Registration

Dear Mr. Gardner:

Zoecon Corporation hereby submits, in triplicate, an Application for Pesticide Registration of Fluvalinate Technical, An Insecticide for Manufacturing Use Only. This is a manufacturing concentrate of the active ingredient RS- α -cyano-3-phenoxybenzyl (R)-2-chloro-4-(trifluoromethyl)-anilino-3-methylbutanoate, also referred to as (α RS,2R)-fluvalinate.

(α RS,2R)-Fluvalinate is the active ingredient in several Zoecon products recently reviewed by the U.S. Environmental Protection Agency. These include:

Mavrik® 2E, For Use on Cotton (EPA EUP No. 20954-EUP-19, 21)

Mavrik AQUAFLOW™ Insecticide (EPA EUP No. 20954-EUP-123)

Mavrik® 2E, Insecticide (EPA Reg. No. 20954-RRL)

CONTENTS

This Application for Registration is organized according to the most recent draft of the EPA's "Guidelines for Registering Pesticides" and includes:

Introduction	Copy of Cover Letter Pesticide Registration Application Form Label Technical Data Confidential Statement of Formula Offer to Pay Statement Certification Statement Method of Data Support Statement
Section A	Product Chemistry
Section B	Proposed Labelling
Section C	Product Toxicology

Please refer to the following EPA Submissions for additional data in support of this registration:

DATE SUBMITTED	PRODUCT	USE	TYPE OF SUBMISSION	FILE SYMBOL	VOLUME/ ACCESSION NO.	DATA
5/8/81	MAVRIK 2E	Cotton	EUP	20954-EUP-19	1/070093	Intro Residue, Tolerances, EUP Program
					2/070094	
2/4/82	MAVRIK 2E	Cotton	EUP	20954-EUP-19	1/070095	Intro
					2/070096	Toxicology
					3/070097	Toxicology
					4/070098	Toxicology
					5/070099	Toxicology
					6/070100	Toxicology
					7/070101	Residue, Proposed Tolerances
4/15/82	MAVRIK 2E	Fruit, Nut, Vegetables	EUP	20954-EUP-21	1/070657	Intro Residue, Env. Chemistry, Metabolism
					2/070658	
6/15/82	MAVRIK 2E	Fruit, Nut, Vegetables	EUP	20954-EUP-21	1/070659	Intro
					2/070660	Toxicology
					3/070661	Toxicology
					4/070662	Toxicology
					5/070663	Toxicology
					6/070664	Toxicology
					7/070665	Toxicology
8/15/82	MAVRIK 2E	Fruit, Nut, Vegetables	EUP	20954-EUP-21	8/070666	Toxicology
					9/070667	Residue, Analytical Chemistry
10/15/82	MAVRIK 2E	Fruit, Nut, Vegetables	EUP	20954-EUP-21	1/070668	Intro, Toxicology, EUP Program
					2/070669	

Mr. Gardner
April 30, 1983
Page 3

DATE SUBMITTED	PRODUCT	USE	TYPE OF SUBMISSION	FILE SYMBOL	VOLUME/ ACCESSION NO.	DATA
4/15/82	MAVRIK 2E	Ornamentals Planting Seed, Non- bearing Trees	Registration	20954-RRL	1/247353	Intro
9/7/82	MAVRIK 2E	Cotton	EUP Amendment	20954-EUP-19	1/	Intro Residue Chemistry
9/23/82	MAVRIK 2E	Ornamentals Planting Seed Non-bearing Trees	Registration Amendment	20954-RRL	1/243458	Intro, Label Residue Chemistry Toxicology
10/11/82	MAVRIK 2E	Fruit, Nut Vegetable	EUP Amendment	20954-EUP	1/248634	Intro Toxicology
11/8/82	MAVRIK AQUAFLOW	Ornamentals	Registration Amendment	20954-123	1/024882	Intro, Chemistry, Toxicology
12/2/82	MAVRIK 2E	Ornamentals Planting Seed Non-bearing Trees	Registration Amendment	20954-RRL	1/243458	Intro, Label Residue Chemistry
2/8/83	MAVRIK 2E	Ornamentals Planting Seed Non-bearing Trees	Registration Amendment	20954-RRL	1/	Intro, Label Residue Chemistry
2/24/83	MAVRIK 2E	Cotton	Registration Amendment	20954-EUP-19	1/249604	Toxicology
4/14/83	MAVRIK 2F	Fruit, Nut Vegetables	EUP	20954-EUP-	1/	Label EUP Program
4/30/83	Fluvalinate	All uses	Supplemental Data	20954	1/ 2/ 3/ 4/	Toxicology Toxicology Metabolism Residue Chemistry
4/30/83	MAVRIK 2F	Planting Seed Non-bearing Trees	Registration	20954-	1/	Intro Label
4/30/83	MAVRIK 2E	Planting Seed Non-bearing Trees	Registration Amendment	20954-RRL	1/	Intro Label
4/30/83	Fluvalinate Technical	Mfg. Use	Registration	20954-	1/	Intro Label Chemistry
4/30/83	Fluvalinate 25% Bulk	Mfg. Use	Registration	20954-	1/	Intro Label
4/30/83	Fluvalinate 80% Concentrate	Mfg. Use	Registration	20954-	1/	Intro Label Chemistry Toxicology

Mr. Gardner
April 30, 1983
Page 4

LABEL

Five copies of the proposed label for Fluvalinate
Technical, An Insecticide For Manufacturing Use Only are
enclosed with this Application.

CONFIDENTIALITY

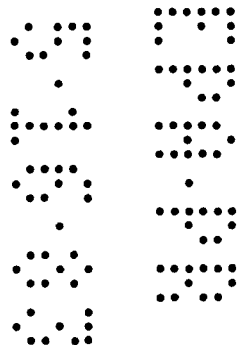
All the information supplied with this Application, except
for the proposed label, is considered confidential and the
property of Zoecon Corporation.

Your cooperation in the timely processing of this
Application will be greatly appreciated. Should you require
any further information concerning this Application, please do
not hesitate to call me.

Sincerely,

Adrienne Ste. Marie
Adriene Ste. Marie
Registration Specialist

(0398E)



FLUVALINATE TECHNICAL

An Insecticide-Acaricide For Manufacturing Use Only

ACTIVE INGREDIENT:

(α RS,2R)-fluvalinate [(RS)- α -cyano-3-phenoxybenzyl
(R)-2-[2-chloro-4-(trifluoromethyl)anilino]-3-methyl-
butanoate]* 85%

INERT INGREDIENTS: 15%

Lot No: _____

Specific Gravity: 1.29 g/cc

Refer to analytical label on this drum for exact analysis of this lot.

*U.S. PAT. 4,260,633 and other Patents Pending.

EPA Registration No. 20954-

EPA Est. No. 1258-NY-3

HAZARDS TO HUMANS

WARNING

OPEN CONTAINER IN WELL VENTILATED AREA
DO NOT BREATHE FUMES

May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash thoroughly before reuse.

FIRST AID

IF IN EYES: Flush with plenty of water. Get medical attention if irritation persists.

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water.

ENVIRONMENTAL HAZARDS

This product is highly toxic to fish. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency.

PHYSICAL/CHEMICAL HAZARD

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
In case of spill or leak, ventilate area well, then soak up with soil or other absorbent material.

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WARRANTY AND CONDITIONS OF SALE

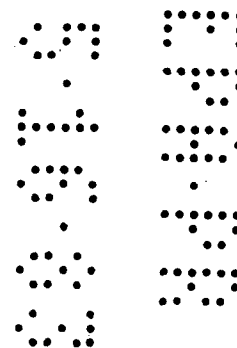
Zoecon Corporation warrants that this product conforms to the chemical description on the label. Zoecon makes no other warranty, express or implied.

ZOECON CORPORATION
AGRICULTURAL CHEMICALS DIVISION
Palo Alto, California 94304

MADE IN USA

NET CONTENTS: 258 Kg (569 lbs.)

68-6100-14 RO
(0399E)





U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE:

☒ REGISTRATION
☐ AMENDMENT

Please read instructions
on reverse before com-
pleting.

SECTION I

1. COMPANY/PRODUCT NO. 20954- *REA* 2. DATE April 30, 1983 3. PRODUCT MANAGER PM-17 4. PROPOSED CLASSIFICATION ☒ GENERAL ☐ RESTRICTED

5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code)

Zoecon Corporation
975 California Avenue
Palo Alto, CA 94304

☐ CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME

Fluvalinate Technical, An Insecticide For Manufacturing Use Only

SECTION II

1. SUBJECT OF AMENDMENT

- ☐ RESUBMISSION IN RESPONSE TO AGENCY LETTER DATED _____
☐ FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____
☐ OTHER (explain below)

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN:

CHILD-RESISTANT PACKAGING ☐ YES ☒ NOUNIT PACKAGING ☐ YES ☒ NO

If YES, unit pkg. wt. _____ No. per container _____

WATER - SOLUBLE PACKAGING ☐ YES ☒ NO

If YES, pkg. wt. _____ No. per container _____

2. TYPE OF CONTAINER

- ☒ METAL
☐ PLASTIC
☐ GLASS
☐ PAPER
☐ OTHER (Specify)

3. LOCATION OF NET CONTENTS

☒ LABEL ☐ CONTAINER

4. SIZE(S) OF RETAIL CONTAINER

200 Liters

5. LOCATION OF LABEL DIRECTIONS

☒ ON LABEL☐ ON MATERIAL ACCOMPANYING PRODUCT

6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT

- ☐ LITHOGRAPH ☐ OTHER (Specify)
☒ PAPER GLUED
☐ STENCILED

SECTION IV

1. CONTACT POINT (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

NAME

Adrienne Ste. Marie

TITLE

Registration Specialist

TELEPHONE NO. (Include Area Code)

(415) 857-1130

2. SIGNATURE

Adrienne Ste. Marie

3. TITLE

Registration Specialist

4. TYPED NAME

Adrienne Ste. Marie

5. DATE SIGNED

April 30, 1983

6. DATE APPLICATION RECEIVED (Stamped)

INSTRUCTIONS

GENERAL

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

1. Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b)).
2. Confidential Statement of Formula (EPA Form 8570-4).
3. Five copies of draft labeling.
4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mock-up of the proposed label. If prepared as a mock-up it should be constructed in such a way as to facilitate storage in an 8 1/2 x 11 inch file. Mock-up labels significantly smaller than 8 1/2 x 11 inches should be mounted on 8 1/2 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

ALL DATA FOR WHICH CLAIMS OF CONFIDENTIALITY ARE ASSERTED MUST BE SUBMITTED, BOUND SEPARATELY AND CLEARLY MARKED AS SUCH.

SPECIFIC

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in BLOCK A, for which you are submitting this application. For applications submitted in connection with NEW REGISTRATION actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

BLOCK A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both REGISTRATION and AMENDED REGISTRATION actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
2. **Date** - Fill in the appropriate date.
3. **Product Manager** - If known, fill in the name and number of the Product Manager.
4. **Proposed Classification** - Specify the proposed classification for this product.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant NOT residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

AMENDMENT INFORMATION

Section II - This Section must be completed for all applications submitted in connection with AMENDED REGISTRATION.

1. **Subject of Amendment** - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements", etc.

PACKAGING AND CONTAINER INFORMATION

Section III - This Section must be completed for all applications submitted in connection with NEW REGISTRATION.

1. **Type of Packaging** - Check the appropriate block if you product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the statement of net contents.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Direction** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product labeling is attached to retail container.

CONTACT POINT

Section IV - This Section must be completed for all REGISTRATION and AMENDED REGISTRATION applications.

1-5. Self-explanatory.

6. EPA Use Only.

EPA Form 8570-1 (Rev. 5-81) REVERSE

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12958)

1. CHEMICAL NAME

2. IDENTIFYING NUMBER

3. ACTION CODE

4. ACCESSION NUMBER

TO BE COMPLETED BY PM

20954-REA

160

250303

5. RECORD NUMBER

97885

6. REFERENCE NUMBER

7. DATE RECEIVED (EPA)

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

TAG

10. PM TEAM NUMBER

17

14. CHECK IF APPLICABLE

☐ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

5-24-83

12. PRIORITY NUMBER

13. PROJECTED RETURN DATE

15. INSTRUCTIONS TO REVIEWER

A. HED ☐ Total Assessment - 3(c)(5)
☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

C. ☐ BFSB
D. ☐ TSS/RD
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

☐ Chemical Undergoing Active RPAR Review
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

See Application

16. RELATED ACTIONS

(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB ☐ EEB ☐ EF ☐ PL
☐ RCB ☐ EFB ☐ CH ☐ BFSB

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MINOR USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY ^{6/24/83} <i>ORU/EGC</i>								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSB	ECONOMIC ANALYSIS								

20. ☒ Label Submitted with Application Attached

21. ☒ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include any Original and 4 Copies of This Completed Form for Each Branch Checked for Review.

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U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (WH-567)
WASHINGTON, D.C. 20460

1. COMPANY/REGISTRATION NO.

2. EPA USE ONLY

20954- *REA***LABEL TECHNICAL DATA**

(See INSTRUCTIONS on back of last part)

3. PRODUCT NAME

F

Fluvalinate Technical, An Insecticide For
Manufacturing Use Only

4. APPLICATION SITES (Check all that apply)		5. PEST TYPE (Check all that apply)		7. USER TYPE (Check all that apply)	
<input type="checkbox"/> 01 CROPS (Fruit)		<input type="checkbox"/> 01 ALGAE		<input type="checkbox"/> 01 UNSPECIFIED GENERAL USE	
<input type="checkbox"/> 02 CROPS (Vegetable)		<input type="checkbox"/> 02 AMPHIBIAN/REPTILE		<input type="checkbox"/> 02 UNSPECIFIED RESTRICTED USE	
<input type="checkbox"/> 03 CROPS (Field)		<input type="checkbox"/> 03 BACTERIA		<input type="checkbox"/> 03 HOMEOWNER USE	
<input type="checkbox"/> 04 CROPS (Spice)		<input type="checkbox"/> 04 BIRDS		<input type="checkbox"/> 04 JANITORIAL USE	
<input type="checkbox"/> 05 CROPS (Nut)		<input type="checkbox"/> 05 FISH		<input type="checkbox"/> 05 PEST CONTROL OPERATOR USE	
<input type="checkbox"/> 09 CROPS (Other)		<input type="checkbox"/> 06 FOULING ORGANISMS		<input type="checkbox"/> 06 COMMERCIAL APPLICATOR USE	
<input type="checkbox"/> 10 SOIL TREATMENT (No crop specified)		<input type="checkbox"/> 07 FUNGI		<input type="checkbox"/> 07 FARMER USE	
<input type="checkbox"/> 20 FOREST	<input checked="" type="checkbox"/>	<input type="checkbox"/> 08 INSECTS AND MITES		<input type="checkbox"/> 08 MEDICAL USE	
<input type="checkbox"/> 30 ORNAMENTALS		<input type="checkbox"/> 09 MAMMALS		<input type="checkbox"/> 09 VETERINARY USE	
<input type="checkbox"/> 40 TURF		<input type="checkbox"/> 10 NEMATODES		<input type="checkbox"/> 10 GOVERNMENT AGENCY USE	
<input type="checkbox"/> 50 STORED PRODUCTS TREATMENT		<input type="checkbox"/> 11 PLANTS	<input checked="" type="checkbox"/>	<input type="checkbox"/> 11 MANUFACTURING USE	
<input type="checkbox"/> 61 ANIMALS (Livestock)		<input type="checkbox"/> 12 RODENTS		8. FORMULATION (Check one only)	
<input type="checkbox"/> 62 ANIMALS (Dairy)		<input type="checkbox"/> 13 SLIME		<input type="checkbox"/> 01 TECHNICAL CHEMICAL	
<input type="checkbox"/> 63 ANIMALS (Pet)		<input type="checkbox"/> 14 SLUGS AND SNAILS	<input checked="" type="checkbox"/>	<input type="checkbox"/> 02 FORMULATION INTERMEDIATE	
<input type="checkbox"/> 64 ANIMALS (Laboratory)		<input type="checkbox"/> 15 VIRUS		<input type="checkbox"/> 03 DUST	
<input type="checkbox"/> 69 ANIMALS (Other)		<input type="checkbox"/> 16 OTHER (Specify)		<input type="checkbox"/> 04 GRANULAR	
<input type="checkbox"/> 71 OUTDOOR (Nocrop Agricultural)				<input type="checkbox"/> 05 PELLETTED/ TABLETTED	
<input type="checkbox"/> 72 OUTDOOR (Resident/Commercial)				<input type="checkbox"/> 06 WETTABLE POWDER	
<input type="checkbox"/> 73 OUTDOOR (Non agricultural)				<input type="checkbox"/> 07 WETTABLE POWDER/DUST	
<input type="checkbox"/> 81 BUILDINGS (Agricultural)		6. MODE OF ACTION (Check all that apply)		<input type="checkbox"/> 08 CRYSTALLINE	
<input type="checkbox"/> 82 BUILDINGS (Commercial)		<input type="checkbox"/> 01 ATTRACTANT		<input type="checkbox"/> 09 MICROENCAPSULATED	
<input type="checkbox"/> 83 BUILDINGS (Food Processing)		<input type="checkbox"/> 02 BIOLOGICAL CONTROL		<input type="checkbox"/> 10 IMPREGNATED MATERIALS	
<input type="checkbox"/> 84 BUILDINGS (Medical)		<input type="checkbox"/> 03 CHEMOSTERILANT		<input type="checkbox"/> 11 SELF-GENERATING SMOKE	
<input type="checkbox"/> 85 BUILDINGS (Residential)		<input type="checkbox"/> 04 DEFOLIANT		<input type="checkbox"/> 12 EMULSIFIABLE CONCENTRATE	
<input type="checkbox"/> 91 EQUIPMENT (Commercial)		<input type="checkbox"/> 05 DESICCANT		<input type="checkbox"/> 13 INVERT EMULSION	
<input type="checkbox"/> 92 EQUIPMENT (Food)		<input type="checkbox"/> 06 FEEDING-DEPRESSANT		<input type="checkbox"/> 14 FLOWABLE CONCENTRATE	
<input type="checkbox"/> 93 EQUIPMENT (Agricultural)		<input type="checkbox"/> 07 GROWTH INHIBITOR		<input type="checkbox"/> 15 SOLUBLE CONCENTRATE	
<input type="checkbox"/> 94 EQUIPMENT (Medical)		<input type="checkbox"/> 08 GROWTH REGULATOR		<input type="checkbox"/> 16 SOLUTION (Ready to Use)	
<input type="checkbox"/> 95 EQUIPMENT (Transportation)		<input type="checkbox"/> 09 POISON (Single dose)		<input type="checkbox"/> 17 OILS (No added pesticide)	
<input type="checkbox"/> 96 LAUNDRY AND DRY CLEANING	<input checked="" type="checkbox"/>	<input type="checkbox"/> 10 POISON (Multiple Dose)		<input type="checkbox"/> 18 PRESSURIZED (Gas)	
<input type="checkbox"/> 97 INDUSTRIAL PRESERVATIVES	<input checked="" type="checkbox"/>	<input type="checkbox"/> 11 PRESERVATIVE		<input type="checkbox"/> 19 PRESSURIZED (Liquid)	
<input checked="" type="checkbox"/> 98 PESTICIDE (Manufacturing only)		<input type="checkbox"/> 12 REPELLENT		<input type="checkbox"/> 20 PRESSURIZED (Dust)	
<input type="checkbox"/> 99 OTHER (Specify)		<input type="checkbox"/> 13 OTHER (Specify)		<input type="checkbox"/> 21 OTHER (Specify)	

REMARKS:

EPA Reg. No. _____

EPA File Symbol 20954-REA

A-1 ADMINISTRATIVE CHECK LIST

We have received your application for registration but cannot process it until the items checked are corrected.

- ____ 1. Please include an Application for Pesticide Registration/Amendment, EPA Form 8570-1. This form is required for all initial submissions, resubmissions (subsequent submissions prior to registration), and amendments.
- ____ 2. Your application for amendment did not identify the EPA File Symbol or EPA Registration Number of the product. Please refer to the applicable EPA File Symbol or EPA Registration Number in all correspondence concerning the product.
- ____ 3. The Data Reference Sheet, EPA Form 8570-20, was not included. This form must be submitted with all applications for new registration, reregistration, and with any other application which requires a change in information previously submitted on the form.
- ____ 4. You must apply separately for registration for each pesticide product.
- ____ 5. You must indicate the proposed classification of the pesticide product in block 4 of the application.
- ____ 6. You must specify the type of container in Section III of the application.
- ____ 7. You must state in Section III, block 1 of the application if child-resistant packaging will be used.
- ____ 8. You must state the name of the pesticide product, not the active chemical, in block 6 of the application.
- ____ 9. You must indicate, in Section III, block 5 of the application, the location of label directions.
- ____ 10. The manner in which the label is affixed to the product must be indicated in Section III, block 6 of the application.
- ____ 11. The application form was not signed (Section IV, block 2). We are, therefore, returning your application.
- ____ 12. The applicant's title must be indicated in Section IV, block 1.

(Over)

A-1 ADMINISTRATIVE CHECK LIST (continued)

- ___ 13. Your application did not include a statement regarding data compensation in accordance with PR Notice 83-1.
- ___ 14. The applicant's name was not printed in Section IV.
- ___ 15. The application date must be indicated in Section IV, block 4.
- ___ 16. Each product must have a different product name. The name listed on the application form is the same as for the product under (EPA File Symbol) (EPA Reg. No.) _____. We are, therefore, returning your application.
- ___ 17. An application for amending the registration which involves a significant ingredient change is considered as an application for the registration of a new product. Therefore, we are returning your application. If you wish to resubmit it, please complete a new EPA Form 8570-1. The product name should be modified so as to be distinguishable from the old product name. You should inform this office of your intentions with respect to the product registered under EPA Reg. No. _____.
- ___ 18. Please clearly indicate the nature of the amendment in Section III, block 1 of the application.
- ___ 19. Two (2) legible and identical copies of the proposed labeling must be submitted. Labeling submitted with the application should be in typewritten draft form. You will be notified if copies of final printed labeling are required.
- ___ 20. The product name on the labeling differs from that stated on the application/letter.
- ___ 21. The Confidential Statement of Formula, EPA Form 8570-4, declaring the name and percentage by weight of each active and each inert ingredient, must be included.
- ___ 22. Declaration of the term "inert ingredients" on the Confidential Statement of Formula is not acceptable. If the complete chemical composition of the product is not known to you, send a separate copy of this form to your supplier, and request him to submit it to us. This form should clearly identify the applicable EPA Registration Number(s)/File Symbol(s).
- ___ 23. The Confidential Statement of Formula was not signed and/or is incomplete. It is, therefore, being returned.
- ___ 24. We have not received the formal authorization from your supplier to use the confidential formulation of your label. We cannot review your label until you furnish this information.

April 30, 1983

Mr. Timothy Gardner (PM-17)
Registration Division (TS-767-C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

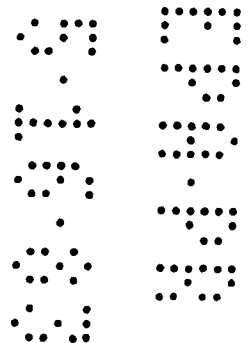
Dear Mr. Gardner:

I understand that the cite-all method of data support is no longer required in order to secure Registration under my pending application for Fluvalinate Technical, An Insecticide For Manufacturing Use Only, identified as 20954- and submitted on 4-30-83. I hereby choose the cite-all method of data support. I hereby submit all the required data compensation forms for that method of support.

Sincerely,

Adrienne Ste. Marie
Adrienne Ste. Marie
Registration Specialist

ASM/vl



U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (TS-767)
WASHINGTON, D.C.

1. EPA FILE SYMBOL/REGISTRATION NO.

20954 -

CERTIFICATION STATEMENT

(Please read instructions on reverse before completing)

2. DATE OF APPLICATION TO WHICH THIS
STATEMENT APPLIES

April 30, 1983

3. PRODUCT MANAGER

PM-17

5. APPLICANT'S NAME AND ADDRESS

Zoecon Corporation
975 California Avenue
Palo Alto, CA 94304

4. PRODUCT NAME

Fluvalinate Technical, An Insecticide
for Manufacturing Use Only

6. I certify that I have notified in writing the companies who have submitted data upon which I have relied to support my application, and that I have offered to:

1. Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended; and
2. Commence negotiations to determine which data are subject to the compensation requirements of FIFRA, and the amount and terms of compensation, if any, due.

7. The companies I have notified are:

- A. ☒ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (see 40 CFR 162.9-5).
- B. ☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product which are *not derived from registered and purchased sources* (see 40 CFR 162.9-8(f)).
- C. ☐ Those companies who have conducted the studies which I have submitted (or cited if conducted with an identical product) (see 40 CFR 162.9-8(e)).

8. SIGNATURE

Adrienne Ste. Marie

9. TYPED NAME AND TITLE

Adrienne Ste. Marie
Registration Specialist

DATE SIGNED

April 30, 1983

INSTRUCTIONS

GENERAL

Use this form to certify that you have made the appropriate Offers To Pay, under any method of compensation, to persons or companies who have submitted data on which you have indicated your application relies.

Thus, you must use this form if you use the Cite-All Method of Compensation (EPA Form 8570-23) or the Combined form of the Alternate Method (EPA Form 8570-22).

Use this form, even if you use the Alternate Method of Compensation (EPA Form 8570-24), if any part of the study you are submitting on your formulation was conducted by another company.

Submit this form *after* making the appropriate Offers To Pay to which you are certifying. You need not submit this form with your application for registration, although you may choose to submit it if you have at that time made the Offers To Pay. If you do not notify companies until after you have submitted your application for registration, you may submit this form separately.

This form must be submitted before your registration will be approved.

SPECIFIC INSTRUCTIONS

1. EPA File Symbol/Registration No. — Enter the file symbol/registration number assigned to this product.
2. Date of Application — Enter the date of the application to which this Certification Statement applies. Do *not* enter the present date if this form is being submitted after the application.
3. Enter the name of the EPA Product Manager assigned to your product, if known.
4. Product Name — Enter the product name of this pesticide as it will appear on the label.
5. Self-explanatory.
6. Self-explanatory.
7. Mark ('X') the appropriate block to indicate the companies you have notified. The block marked must correspond with the information on the Offer To Pay submitted with your application for registration.

Block A corresponds to the Cite-All Offer To Pay Statement (EPA Form 8570-23).

Block B corresponds to the Combined Offer To Pay Statement (EPA Form 8570-22).

Block C corresponds to the Alternate Method Offer To Pay Statement (EPA Form 8570-24).

8. Self-explanatory.

9. Self-explanatory.



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAM (TS-767)
WASHINGTON, D.C. 20460

OFFER TO PAY STATEMENT
Cite-All Method of Compensation

(Please read instructions on reverse before completing.)

1. DATE

April 30, 1983

2. EPA REGISTRATION NO./FILE SYMBOL

20954-

3. PRODUCT MANAGER

PM-17

4. NAME AND ADDRESS OF APPLICANT (Write or print within the corner marks; include zip code.)

Zoecon Corporation
975 California Avenue
Palo Alto, CA 94304

5. PRODUCT NAME

Fluvalinate Technical, An Insecticide For Manufacturing Use Only

6.

This is an Offer to Pay Compensation under 40 CFR 162.9-4 and -5 in connection with an Application for Registration.

Applicant offers and agrees to pay compensation to other persons with regard to the approval of this application, to the extent required by Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA).

Applicant acknowledges that for purposes of FIFRA 3(c)(1)(D) this application, and any resulting registration, relies on the following data:

1. Any data submitted or specifically cited by the applicant; and
2. Each other item of data in the Agency's files which:
 - a. Concerns the properties or effects of:
 - (1) Applicant's product;
 - (2) A product identical or substantially similar in composition to applicant's product; or
 - (3) One or more of the active ingredients of applicant's product for which EPA has not published a final generic standard; and
 - b. Is one of the types of data that EPA would require to be submitted for scientific review if the application sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and uses identical or substantially similar to those of the applicant's product, under the data requirements in effect on the date EPA approves applicant's present application.

12. DATE APPLICATION
RECEIVED (EPA use only —
stamped)

7.

☒ I have notified the appropriate companies and attached the Certification Statement.

☐ The Certification Statement will be submitted prior to registration.

8. NAME OF APPROVING OFFICIAL

Adrienne Ste. Marie

9. TITLE

Registration
Specialist

10. SIGNATURE OF APPROVING OFFICIAL

Adrienne Ste. Marie

11. DATE SIGNED

April 30, 1983

12/81

Record Number _____

88 Reference Number _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

Input Date _____

Reviewer _____

File Symbol/Reg. No. 20954-REA *PM * 89 ID No. * 08 Action Code _____

10 Descriptor (Amend/Resubmissions only) _____

05 Intrastate _____ Yes _____ No _____ Intrastate Company and
Call-in _____ Accession Number _____15 Child-Resistant _____ (C) Certification
Packaging _____

* 20 Registration Type

____ (S) Service Person _____ (N) Not-
Applicable

____ (1) Conditional

____ (R) Non-Residential
Use Only

____ (2) Unconditional

25 Proposed Classification

30 Final Classification

____ (R) Restricted

____ (R) Restricted

____ (N) Not Classified

____ (G) General

____ (G) General

* 35 Date on Application

* 04 EPA Received Date

* 40 PM Received Date

MO DAY YR
04 20 83MO DAY YR
05 16 83MO DAY YR
5 19 83** 45 Date Reviewable Data
Package ReceivedMO DAY YR

** 50 Product Type (circle one): A AR B/F D DE DF F H I IR PGR R S

** 55 Priority (circle one): 1 2 3 4 5 6 7

** 60 Applicant: _____

** 65 Chem.Code (1) _____ Chem.Name (1) _____

Chem.Code (2) _____ Chem.Name (2) _____

Chem.Code (3) _____ Chem.Name (3) _____

Chem.Code (4) _____ Chem.Name (4) _____

** 75 Proposed Use: _____

80 Method of Support

85 Certification Statement

____ (1) Cite-all

____ (4) Not Applicable

____ (1) Yes

____ (3) Not Applicable

____ (2) Alternate

____ (5) Not Submitted

____ (2) Not Submitted

____ (3) Combined

** [90] Petitions Pending (1) (2) (3) (4)

Date Sent to Federal Register Section for Publication (5)

** [95] Notice of Receipt MO DAY YR ** [100] Notice of Publication MO DAY YR

Reviews Requested:

[1] DIV/BR	DATE SENT [2]	DUE DATE [3]	DATE RETURNED [4]	RESPONSE CODE [6]	RESPONSE DATE [7]
HED					
EFB					
RCB					
EEB					
TB					
RD					
PM					
PL					
CH			6/27/83	AL/020	
EF					

[110] Conditional Registration Data Required (Enter due dates only):

(1) MO DAY YR (2) MO DAY YR (3) MO DAY YR
(4) MO DAY YR (5) MO DAY YR (6) MO DAY YR

* [108] Status: _____

FINAL * [115] Response ACTION Code _____ * [120] Response Date MO DAY YR

75-Day Response Due Date: (Y) (N)

Complete only these items for resubmission.
Complete for New Chemicals/New Uses.

PRODUCT NAME:

PRODUCT
MANAGER

PESTICIDE TYPE CODE:

TOXICITY CATEGORY:

FORM CODE:

DATE REGISTERED:

MM DD YY